10/2011
October

CHEManager EUROPE

THE NEWSPAPER FOR THE CHEMICAL AND LIFE SCIENCE MARKETS

Markets and Companies

Interview with Styrolution's CEO Roberto Gualdoni

Page 5

Markets and Companies

Expert Peter Pollak discusses the fragmented world of fine chemicals

Pages 8 and 14

Newsflow

Market and Companies:
Haltermann sold to H.I.G Europe, Dr. Uwe Nickel named new CEO.

DuPont seeking buyers for two separate businesses: a polyester-film joint venture and one that makes powder-based paint.

Bayer and Yunona Holdings have entered a memorandum of understanding to manufacture drugs in Russia.

AstraZeneca has announced it will be laying off about 400 employees in the U.S., primarily at its headquarters in Wilmington, Del.

Lanxess has announced three investments totaling upwards of €30 million in Brazil.

Syngenta has posted a 21 % rise in its Q3 results over last year.

More on **Page 2** ▶

Under Construction:
Both Solvay and Evonik are building hydrogen peroxide plants; Solvay in Thailand, Evonik in China.

The first production facilities in the $1.4 billion expansion of BASF-YPC Company have now begun operations.

More on **Page 5** ▶

People:
Dr. Thomas Büttner became AllessaChemie's president and CEO on Oct. 1, taking over from Almuth Poetz.

Michael Träger, managing director and COO of Vestolit, has been reelected as chairman of Euro Chlor for another one-year term.

Kenneth Frazier will be succeeding Merck & Co. chairman Richard Clark on Dec. 1.

Linde has appointed Thomas Blades as a new member of the executive board. Blades will succeed J. Kent Masters.

Events:
There are several industry events coming up in November and December. Check out our event listings for more details.

More on **Page 19** ▶

An Industry Full of Opportunity

CPhI Highlights the Latest Trends in Pharma

Markus Blocher
CEO, Dottikon

API

… Chemical exclusive synthesis partners need to possess a versatile technology portfolio like a Swiss army knife and be as precise and reliable as a Swiss watch.

Jean Bléhaut
Director of Marketing & Business Development, Novasep

Custom Manufacturing

Over the years, the new synthetic molecules developed in the pharmaceutical industry have become larger and more challenging to synthesize.

Wolfgang Schmitz
CEO, Saltigo

Custom Manufacturing

…We see also growth potential in the pharmaceutical sector, because big pharma companies are outsourcing more and more to concentrate on their core strengths and emerging pharma companies continue to drive new drug developments through innovation.

Dr. Andreas Dietrich
Vice President Launch and Strategic Products, Boehringer Ingelheim

APIs

While corresponding quality and regulatory understanding was still in need of development, today's Asian manufacturers have become better at responding to needs which go beyond price.

Dr. Jörn Winterfeld
Director Business Line Pharma/Agro at Wacker Biosolutions, Wacker

Fine Chemicals

Consolidation in the fine chemicals industry will continue, since it is a very fragmented industry. Many small players may vanish or merge to attain the so-called critical mass. This trend includes producers in China.

Dr. Martin Wienkenhöver
CEO, CABB

Fine Chemicals

…We see a strong growth in the outsourcing of fine chemicals – especially of more challenging chemical syntheses.

Robert Hardy
CEO, Aesica

General

In 10 years, our industry will be much stronger, competitive and diverse with the most significant contribution to the pharmaceutical market coming from emerging economies such as Brazil, Russia, China and India.

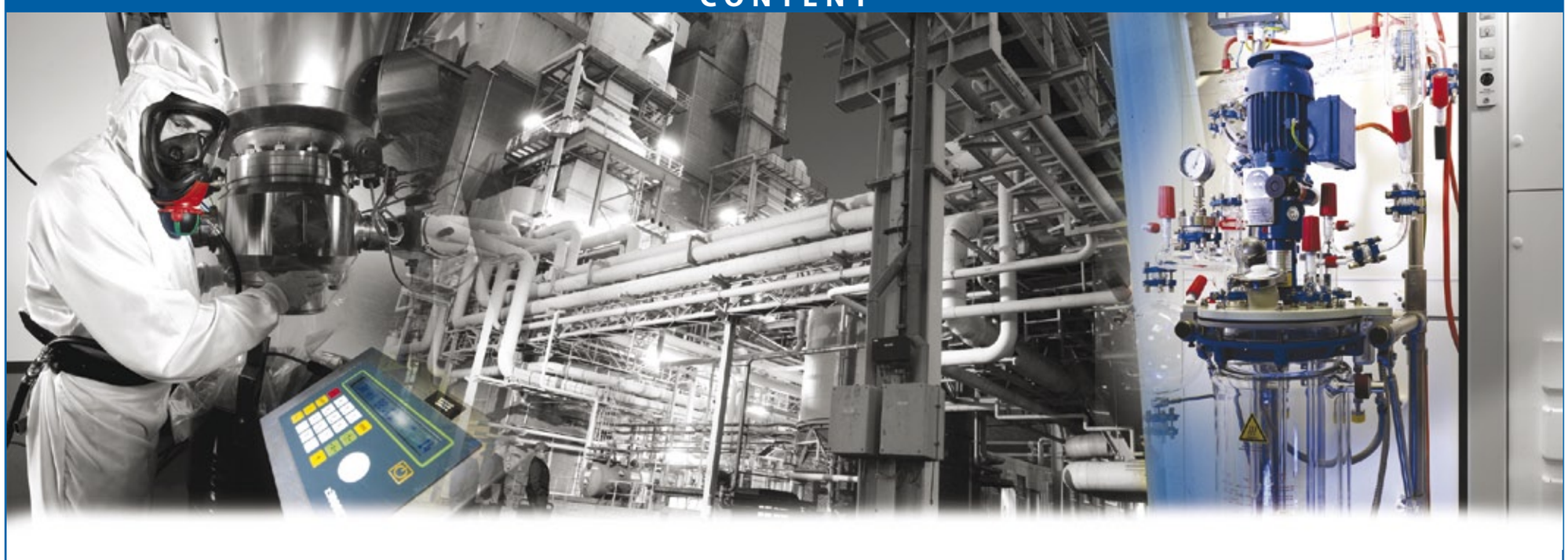
Dr. Ralf Fink
Vice President and Head of Pharma Ingredients at BASF

General

Cost pressure, strong growth in emerging countries, ongoing market consolidation as well as the emergence of new regional or even global players and a significant higher demand for performance excipients are scenarios we want to be prepared for.

GIT VERLAG · PF 11 05 64 · 64220 Darmstadt · Pressepost · DPAG· Entgelt bezahlt · 78719

CONTENT



AkzoNobel Completes Schramm Holding Acquisition

AkzoNobel has completed its acquisition of more than 95% of the shares of coatings manufacturer Schramm Holding. Based in Germany and listed on the Hong Kong Stock Exchange, Schramm manufactures and markets coatings for plastics, metals and electrical insulation as well as coil coatings for aluminum. They achieved global revenues in 2010 of €115 million and employ around 800 people. In addition to the Schramm deal, the company expects to finalize the acquisition of Korean SSCP's coatings business as of Nov. 1. SSCP was also the majority shareholder of Schramm until the Akzo deal. ■

Lanxess to Invest €30 Million in Brazil

Lanxess has announced three investments totaling €30 million in Brazil. The company said investments will support the growing trend toward green mobility in the Latin American country. The investments include the construction of two new plants at the company's Porto Feliz site in the State of São Paulo. One plant will produce the high-tech engineering plastics Durethan and Pocan; the plant will have an initial capacity of 20,000 metric tons per year and will go on stream in mid-2013. The other plant will produce the rubber additives Rhenogran as well as Rhenoshape curing bladders.

In the third investment, Lanxess is re-engineering parts of its plant in Triunfo, Rio Grande do Sul, in order to produce EPDM rubber from bio-based ethylene. The Brazilian company, Braskem S.A., will supply the ethylene, derived from sugarcane, by pipeline as of November. ■

AstraZeneca to Cut 400 U.S. Jobs

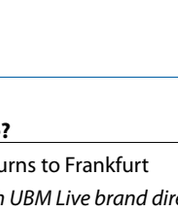
AstraZeneca has announced plans to cut about 400 employees in its U.S. commercial operations, citing a need to reduce costs. The company said the jobs are mainly at its U.S. headquarters in Wilmington, Del., and some field-based, non-sales roles. The company has about 14,400 employees in North America. About 70 of the estimated positions to be eliminated will come from existing vacancies, leaving about 330 current workers affected by the cuts, said spokesman Tony Jewell. The specific jobs targeted haven't been identified yet. All decisions will be finalized by early December.

"The changes will enable the company to compete in a challenging environment, including pricing pressures and the continuing growth of generics medicines," the company said in a press release.

Several of AstraZeneca's best-selling drugs face the loss of patent expiration in coming years. ■

Haltermann Sold to H.I.G Europe

Haltermann, a subsidiary of Dow, has been acquired by H.I.G. Europe, the European arm of H.I.G. Capital. The CEO of the new Haltermann is Dr. Uwe Nickel, formerly board member of Clariant and head of the chemical practice of the consulting firm Arthur D. Little. At production sites in Hamburg and Speyer, Germany, Haltermann produces complex test and specialty fuels as well as various solvents based on hydrocarbons with short to medium chain length, all with narrowly defined specifications. Haltermann is also a supplier of high-purity n-, iso- and cyclopentanes employed as blowing agents in the production of polystyrene and polyurethane foams. ■



Dr. Uwe Nickel
CEO, Haltermann

ECHA Board Decisions in Fee Disputes

The European Chemicals Agency's (ECHA) board of appeal has published its first two final decisions on appeals against decisions adopted by ECHA under the Reach Regulation 1. In both cases, the appellants had paid the fee required for the registration of a substance after the expiry of the deadlines set by the agency. According to the Reach Regulation and the associated Fee Regulation 2, non-payment of the registration fee by the set deadline will result in the registration being rejected with any late fee not being refunded. While both cases dealt with the late payment of the registration fee, the particular circumstances of the cases are different. The board of appeal decided in favor of the appellant in one case and in favor of ECHA in the other. In one case, the appellant wanted a refund of the registration fee; the board ordered ECHA to refund the money. In the other case, the appellant asked to board to annul the decision rejecting the registration. However, the board sided with ECHA, stating that the agency had acted correctly in rejecting the registration. ■

Syngenta Posts Increase in Q3 Sales

Syngenta posted third-quarter sales of $2.66 billion, an increase of 21% from last year's $2.2 billion. At constant exchange rates, sales rose 16%. Going ahead, for the full year, the company said it expects substantial top line growth, higher profitability at constant exchange rates and a significant increase in free cash flow. ■

Bayer Joins Yunona Holdings For Drug Manufacturing

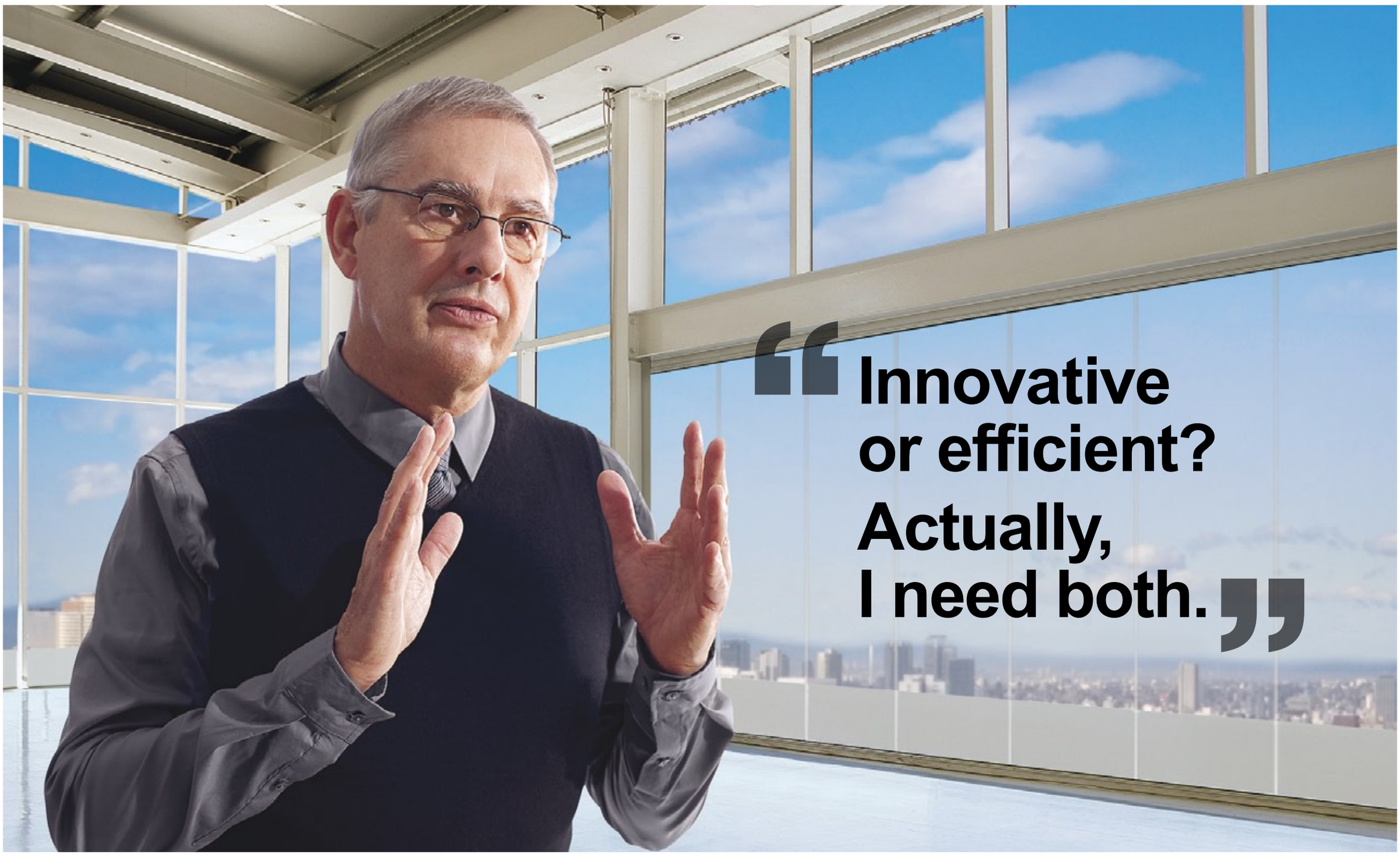
Bayer and Yunona Holdings, representing the Ural Pharmaceutical Cluster (UPC) of Russia have entered a memorandum of understanding to manufacture drugs in Russia. The companies said they intend to establish themselves in the fields of production, marketing and distribution of pharmaceutical products in Russia, the website inpharm.com reported. The cluster has received funds worth 27.3 billion rubles (around $860 million) from Russia's economic development program between 2010 and 2015. ■

Ashland Opens Mumbai Technical Center

Ashland has opened a new technical center in Mumbai, India. The company said the new Ashland Technical Center will develop additives and ingredients that deliver high-performance characteristics sought after by coatings and construction industry professionals. The technical center offers the latest technologies for rheological additives, surfactants, foam-control agents, buffers for water-based paints, additives for cement dry admix and for construction chemicals. Plans call for the technical center to be expanded to offer solutions for the personal care industry in early 2012. ■

DuPont Looking to Sell Teijin JV

DuPont said it is seeking buyers for two separate businesses, a polyester-film joint venture and one that makes powder-based paint. According to a Bloomberg report, DuPont is also considering buying the 28% stake it doesn't already own in Solae, its soy-products joint venture with Bunge. It added that DuPont has put that process on hold while it decides whether to merge the business with Danisco, a Danish-based maker of food ingredients and enzymes. ■



DOW CORNING

XIAMETER® from DOW CORNING

That’s why the *Dow Corning*® brand focuses on your toughest challenges.

Every day, we’re helping customers solve complex challenges that make a real difference. Whether helping make solar panels more cost-effective or inspiring more energy-efficient and comfortable building designs, we’re always innovating.

That’s why the XIAMETER® brand makes buying standard silicones easy and efficient.

Our Web-enabled XIAMETER brand brings you more than 2,100 quality products at market-based prices. It’s everything you need to efficiently manage your inventory, protect cash flow and hold down costs.

Dow Corning® innovation. XIAMETER® efficiency. Two ways Dow Corning Corporation helps silicones transform your business, and the world. *Learn how we help the world’s architects save energy and improve comfort in their new building designs.* Download the case study and see others at **dowcorning.com/transform**

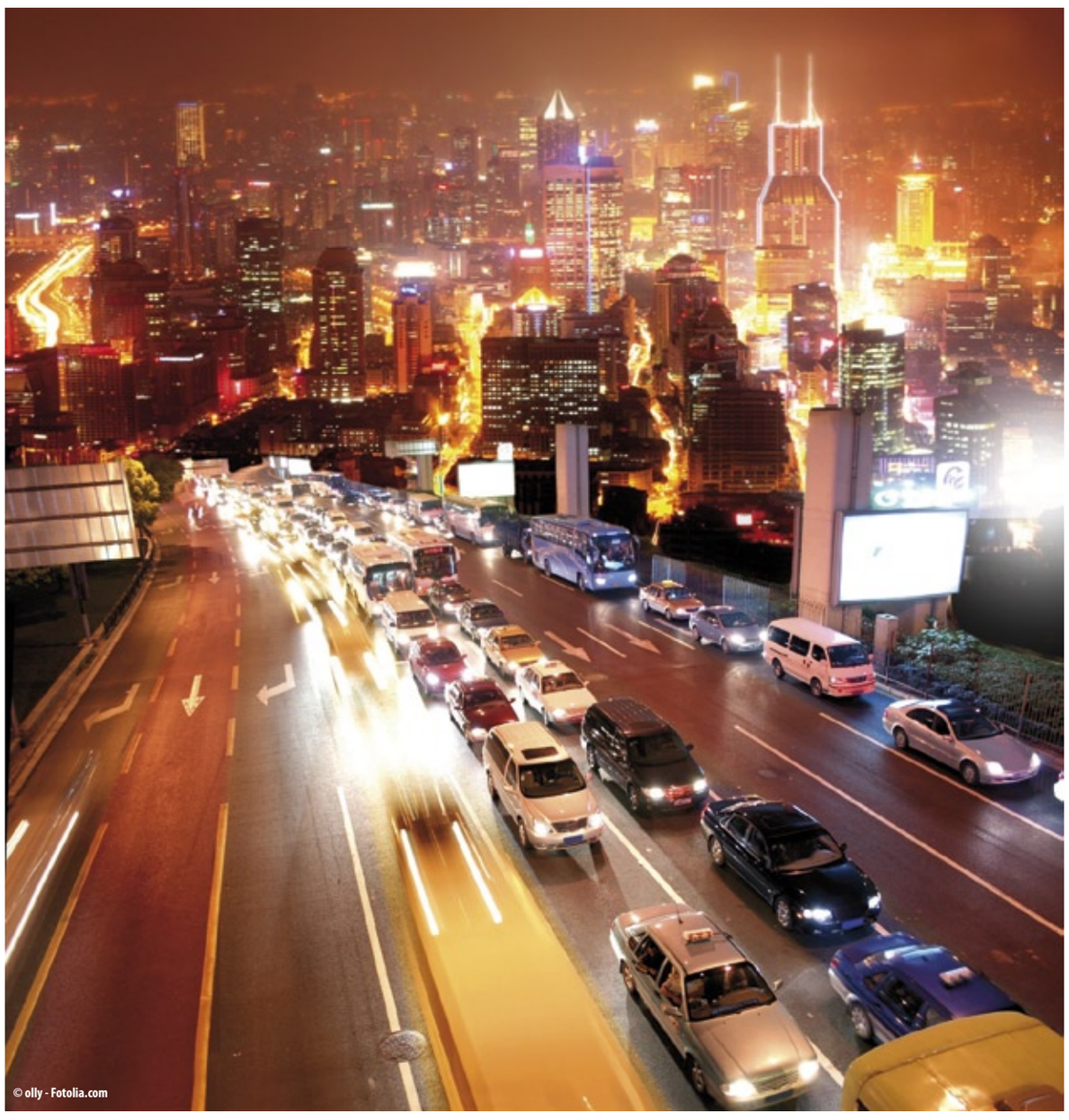
We help you invent the future.™

DOW CORNING

Specialty Chemicals In China

What's so Special About It?

Faster Than Industry Average – Generally, the chemical industry in any given country starts with basic chemicals and moves on to higher-value chemicals later. Accordingly, in China, more than 50 % of chemical sales come from basic chemicals, while in Japan the figure is around 40 %. As China's development proceeds, specialty chemicals will therefore grow faster than the chemical industry average. According to the National Bureau of Statistics of China, revenue growth in specialty chemicals was +21 % for specialty chemicals but only +7 % for the average of the chemical industry. So China's specialty chemicals segment is highly attractive due to its high growth rate. This attractiveness is also reflected in direct investment of foreign specialty chemicals companies.


© olly - Fotolia.com

© Alex Klein - Fotolia

High Growth, High Fragmentation

Dr. Bernhard Hartmann
Managing Director,
A.T. Kearney China

Dr. Kai Pflug
CEO, Management
Consulting – Chemicals

Specialty chemicals companies in China have a somewhat higher profitability than the chemicals average. However, this difference is not huge, most likely as other factors such as the small average company size in specialty chemicals lower the average profitability.

Another characteristic is the intense fragmentation of the specialty chemicals industry. There are almost 10,000 domestic specialty chemicals companies in China, far more than for any other chemical segment. Even the biggest specialty chemical companies such as Zhejiang Chuanhua account for far less than 1 % of the total segment sales. And clearly China does not yet have companies that are as prominent as global leaders such as BASF, Clariant, DSM, Evonik, Rhodia or Wacker.

Domestic specialty chemicals companies have a low average technological level. This refers to all relevant aspects such as their R&D level, their portfolio, their level of customer service and their capability to provide complete solutions to customers. Therefore they cannot fulfill the needs of the domestic Chinese market. In many segments, China relies on either locally produced chemicals of MNCs or even on imported materials for high-end chemicals.

Probably as a consequence, government policy is promoting a gradual shift of the chemical industry towards specialty chemicals. This is part of a general trend to move away from large-scale and often polluting primary chemicals to high value-added, high-end chemical products.

Limited Presence of Big Chinese Players …

Given the attractive market conditions, it is surprising that there are no truly big domestic Chinese specialty companies. Even the biggest domestic players have market shares well below 1 % of the total specialty chemicals market and sales far below one billion dollars. Given that individual business units of multinational players often achieve far higher revenues, the key question is what keeps Chinese companies from becoming truly relevant players in specialty chemicals. Likely reasons are:

Lack of strong R&D competence: China's chemical industry is still at a relatively early development stage. Domestic companies have not yet accumulated the wealth of knowledge that enables Western companies to continuously pursue innovation. Furthermore, the mindset of Chinese companies sometimes seems to be too focused on physical assets rather than on intellectual property. This may be a consequence of the somewhat limited protection of intellectual property in China.

Lack of long-term thinking: Chinese chemical companies sometimes lack the necessary longer-term thinking to pursue an area such as specialty chemicals, in which any success will only come after years of efforts to establish the business.

Lack of global reach: Most Chinese chemical companies so far simply lack the marketing and sales network to market products globally. This is not a problem for basic chemicals with a strong domestic demand, but a severe limitation for smaller markets that need to be penetrated globally to reach a profitable level of sales.

Lack of size: This is necessary not only due to the need for global presence, but also as customers more and more expect specialty chemicals companies to provide complete solutions to an industry. The intense fragmentation of the domestic specialty chemicals industry is a major obstacle to reaching critical size. Major Chinese companies prefer to focus on basic chemicals that offer less fragmented and less complex markets which at the same time are much larger.

… And Why This Will Change

Despite these reasons, it is surprising that so far no major Chinese chemical company has established itself as a major player for specialty chemicals. After all, a domestic player should enjoy the higher growth profitability of the segment and also have a number of advantages compared to multinationals:

Specialty chemicals is relatively labor intensive, allowing a Chinese player to benefit from lower labor cost. This is relevant even if multinational companies start to produce specialty chemicals in China, as their costs are generally higher.

Furthermore, success in specialty chemicals depends on understanding specific markets and customers, and providing localized services to them. This should also be easier to be achieved by a truly local company than by a multinational.

"Given the attractive market conditions, it is surprising that there are no truly big domestic Chinese specialty companies."

Finally, while the market for petrochemicals in China is fairly consolidated and dominated by just three companies, the fragmentation of the specialty chemicals sector should allow a determined company to become a leading player comparatively easily. After all, currently most Western chemical executives would probably find it difficult to name just one domestic Chinese specialty chemicals company. The field for any contender thus is relatively open.

Which Companies Will Make It?

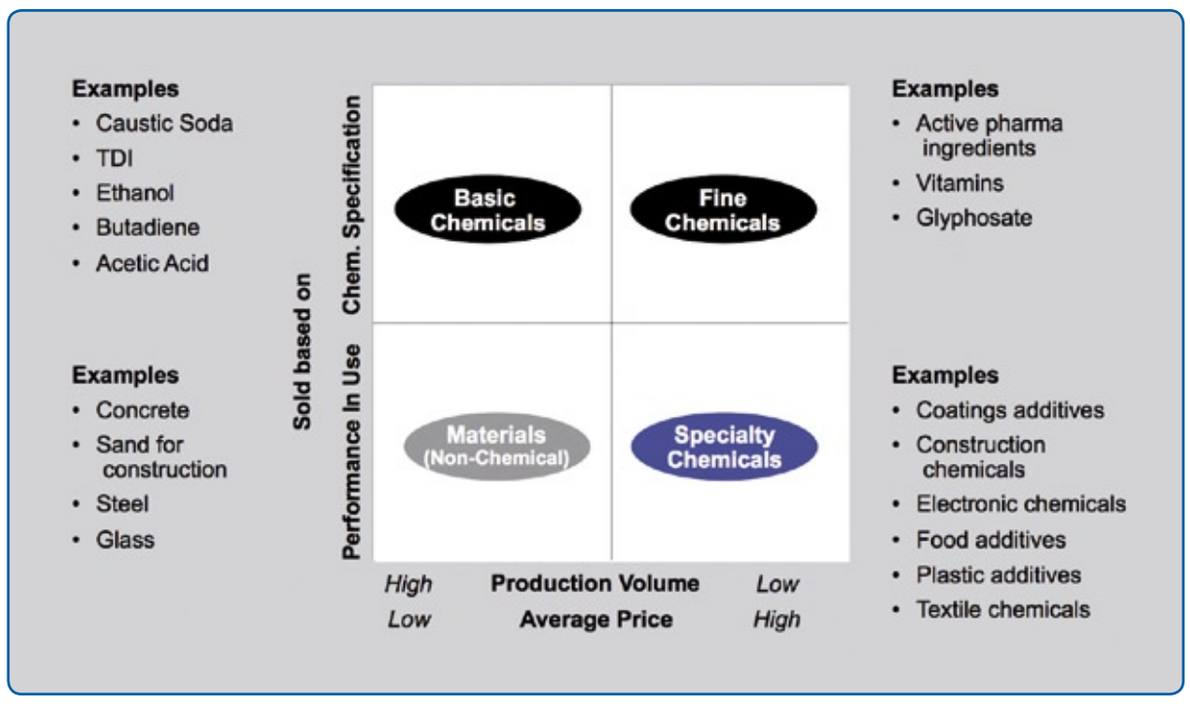
That said, obviously not every Chinese chemical company has the qualities to become a leader in specialty chemicals. Indeed, there are several qualifications that should be met. The company should have a certain size already in order to reach critical mass quickly, and at the same time should be willing to be focused. It will probably not be possible to become the domestic specialty chemicals champion while at the same time still pursuing several other strategic goals.

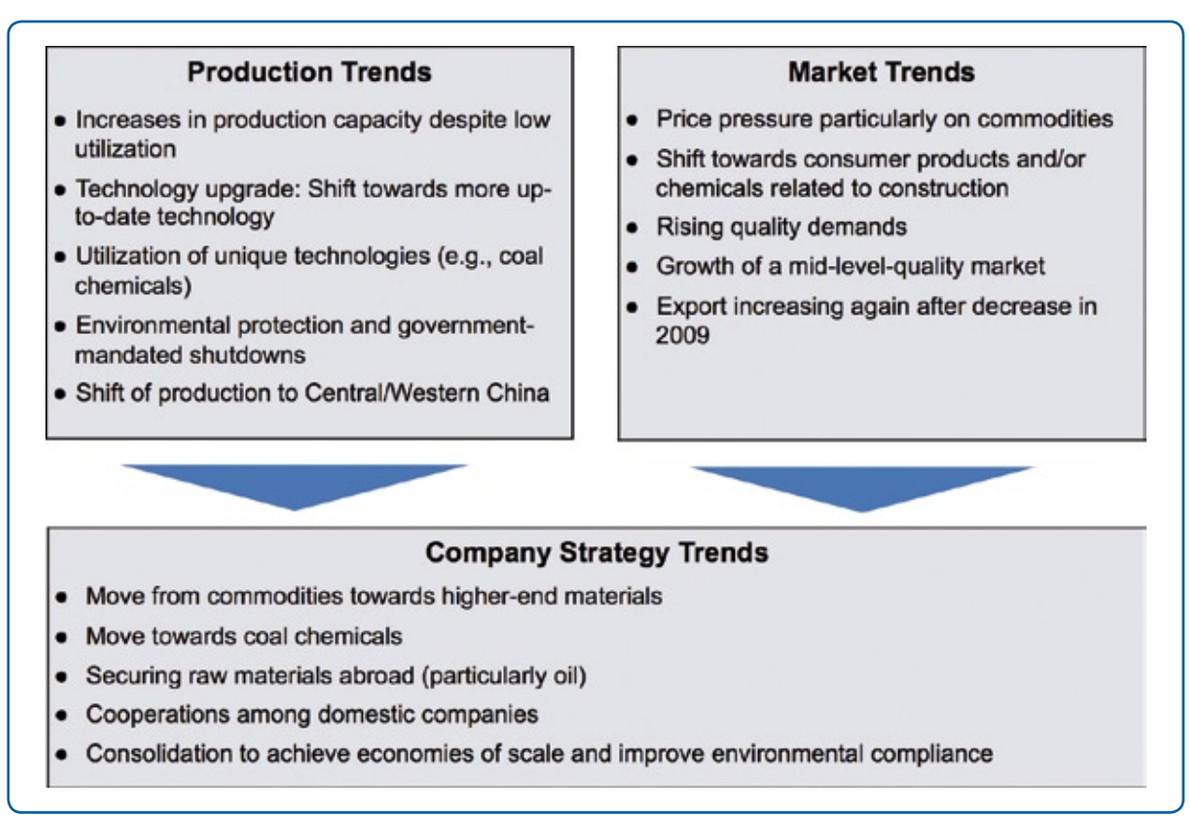
Furthermore, the company should have a mindset that encourages innovation and research, focusing more on intellectual property than on physical assets and be willing to invest in providing technical service.

Finally, the company should ideally already have some international experience as a successful specialty chemicals company will need to target global markets.

What Will Happen Next?

It is to be expected that a few Chinese companies will come to realize the opportunities of becoming a leading player in specialty chemicals. This will first require establishing a clear specialty-focused strategy, which may not be easy given the relatively opportunistic approach of Chinese companies to business planning. In addition, it will be necessary to quickly expand the business. Relying on internal growth alone will not be sufficient as the current gap in the specialty chemicals industry will not be there for more than a few years. Domestic mergers and acquisitions also probably will not be sufficient to become a leading player as most domestic acquisition targets themselves lack size and deep specialty chemicals expertise. This leaves overseas acquisitions. Though by far the most risky and expensive, this is also the approach most likely to work. The current gaps of Chinese chemical companies particularly in the areas of technological knowledge, R&D capability and global reach are best filled by the acquisition of global players or subunits of such players.





Terminology

Throughout this article, the term "specialty chemicals" is used in its European definition. That is, specialty chemicals are low-volume chemicals sold based on their performance in a specific application. This is in contrast to the definition commonly used in China, where the terms "specialty chemicals" and "fine chemicals" are more or less used interchangeably. In other words, in China only the dimension of production volume is used to distinguish between basic chemicals and fine/specialty chemicals, while in Europe (and in this article) the second dimension of whether a chemical is sold based on performance or on specification is used to distinguish between specialty and fine chemicals.

Contacts:
Dr. Kai Pflug
Management Consulting – Chemicals
Hong Kong, China
Tel.: +86 1 36 81 87 39 92
kai.pflug@mc-chemicals.com
www.mc-chemicals.com

Dr. Bernhard Hartmann
A.T. Kearney China
Shanghai, China
Tel.: +86 21 61 82 20 06
bernhard.hartmann@atkearney.com
www.atkearney.com

chemanager-online.com/en/tags/china

Dedicated To Styrenics

Styrolution Starts Operations, Positioned for Profitable Growth and Long-term Success

High Goals – On Oct.1, Styrolution officially started operating as an independent company, following the approval of the relevant antitrust authorities. The new company is a 50:50 joint venture between BASF and INEOS, comprising the key styrenics activities of the two partners. The company name, which is a combination of the words "styrenics" and "solution" implies that the world's new leading styrenics supplier with pro forma combined sales in 2010 of €6.4 billion is determined to give its customers a competitive edge, says Styrolution's CEO Roberto Gualdoni. Dr. Michael Reubold spoke with him right after the launch of Styrolution.

CHEManager Europe: Mr. Gualdoni, what is the underlying strategy of the creation of Styrolution? Do we have to think of it as a mere pooling of resources or even a consolidation of capacities?

R. Gualdoni: No, neither of these reasons was a relevant factor for the formation of Styrolution. Our objective as a company is to be and remain a strong leader in our markets globally, and we are excellently positioned for profitable growth and long-term success. We have a global footprint; we are going to be a formidable player in the fields of styrenics; we have all available technologies of relevance in the industry; we have plants working in each region; we have an experienced team; and we have low financial leverage. This is a good basis for the start going forward. This company is built to last.

Can you give us a brief overview about your product portfolio? What are your market positions in these respective areas?

R. Gualdoni: Styrolution is the only one of the key players dedicated entirely to styrenics. We are actually marketing styrene monomer, polystyrene, ABS – acrylonitrile butadiene styrene – and certain copolymers, most of them well-known in the market, for instance SBC – styrene-butadiene block copolymers. We also have other styrene-based copolymers like SAN, AMSAN, ASA, MABS, and certain copolymer blends like polyamide ABS, ASA polycarbonate, ABS polycarbonate. I think all in all we have the broadest product portfolio in the industry when it comes to styrenics. Styrolution holds global number one positions in styrene monomer, polystyrene, SBC, SAN, AMSAN, ASA, MABS and copolymer blends, and a number two position in ABS. So, we are very well positioned to reap the benefits of that.

Your portfolio does not include businesses with expandable polystyrene and extruded polystyrene foam. What is the reason behind this?

Roberto Gualdoni
CEO, Styrolution

R. Gualdoni: The EPS business with expandable polystyrene, as well as the XPS business with extruded polystyrene foam remain with BASF. This is part of a long-term strategy of our mother companies. The charm of leaving the EPS and XPs activities within BASF is that the production of these materials in the Ludwigshafen Verbund site is self-supported. This way we reduce the complexity of the whole system in terms of Styrolution, too.

From a geographical point of view, almost 50% of Styrolution's revenues come from Europe. What is your strategy to defend your leading position in Europe, while at the same grow your businesses in other regions?

R. Gualdoni: With our global headquarters in Frankfurt, Germany, regional headquarters in Channahon, U.S., and Singapore and with 17 manufacturing sites across 10 countries, Styrolution has a global market presence. We have our "in the region for the region" approach, which allows us to always be close to our customers. In fact, we do have a very strong position in Europe, which stands for 48% of our turnover. But we also have a very good position in the Americas, be it in the U.S. or in Mexico. NAFTA is well covered from the point of view of Styrolution. And I think we also have a very good starting position in Asia with almost a quarter of our turnover being made in this region today. Obviously, when it comes to our position in Europe, we are near to the customer. In terms of the other geographies I think there is a three-phase scenario: At the beginning there will be the integration of these heritage businesses. Then we would have to go through an evaluation and value-extraction of what we have been given. And the third phase would be growth. And with the capabilities that we have we can grow in any polymer in the developing world and rather with the specialties in the developed world.

"This company is built to last."

Innovation is certainly key to fulfill your customers' requirements and to add new applications for styrenics. How do you integrate the R&D activities of BASF and INEOS to get the maximum out of the two R&D cultures?

R. Gualdoni: We are at the moment in a period in which we have to understand each other's businesses. The idea is that after a certain time, we will have a very independent R&D, also independent in the cultural aspects and the philosophy of the R&D from both mother companies. What we are aiming at is more of process innovation in terms of commodities, I think we still have something which can be done, without excluding absolutely that there might be some tweaking on the product area for the commodities. Whereas, when it comes to our specialty part we are much more able to go with the customer all the way through and deliver customized products. That is going to be the main point of our research going forward. Customer nearness, understanding what the needs are going forward, and understanding that having all the technology base out there we can make something better, much more than one plus one in the area of R&D.

chemanager-online.com/en/tags/styrolution

Solvay Commissions HP Plant

Solvay announced that MTP HPJV (Thailand), its hydrogen peroxide joint venture with Dow, has successfully commissioned the largest hydrogen peroxide (HP) plant in the world. The production process of the new plant in Map Ta Phut, Thailand, has a capacity of over 330,000 tons per year of hydrogen peroxide at 100% concentration and serves mainly as a captive raw material source for the manufacture of propylene oxide (PO) by Dow and Siam Cement Group (SCG). Propylene oxide is primarily used to produce propylene glycol, polyurethanes and glycol ethers. It is the second world-scale HP plant dedicated to PO production, the first being the 230,000 tons HP plant (Antwerp, Belgium) commissioned at the end of 2008, which serves a Dow and BASF HPPO plant. Producing PO with HP offers unique and sizeable economic and environmental benefits compared with conventional propylene oxide production technologies. ■

BASF-YPC Expansion Plants Onstream

The first production facilities in the $1.4 billion expansion of BASF-YPC Company have now begun operations. Along with the successful completion of the steam cracker expansion, the newly constructed butadiene extraction plant and the non-ionic surfactants plant are now operational. These plants are part of a $1.4 billion investment project which broke ground in September 2009. The project includes the expansion of the existing steam cracker, from 600,000 tons/year to 740,000 tons/year of ethylene, the expansion of three existing plants, and the construction of ten new plants. The products of this second phase will serve multiple industries such as agriculture, construction, electronics, pharmaceutical, automotive and chemical manufacturing. The bulk of the remaining plants are expected to come on-stream around the end of 2011. ■

Evonik to Build HP Plant in China

Evonik is investing more than €100 million to build a new production plant for hydrogen peroxide (H_2O_2) in Jilin Province in northeastern China. Scheduled to be completed by the end of 2013, the plant will boast an annual production capacity of 230,000 metric tons, thus increasing Evonik's current overall annual capacity of around 600,000 tons for H_2O_2 production by nearly 40%. Evonik will supply its H_2O_2 from Jilin directly to the adjacent propylene oxide plant run by Jishen Chemical Industry Co., Ltd. via a pipeline that will link the two facilities. A long-term supply agreement has already been concluded between the companies. ■

Solvias, RohnerChem Join for Custom Research, Manufacturing Services

Solvias and RohnerChem announced a partnership for custom research and manufacturing services. The preferred but non-exclusive partnership closes the chain of services from route scouting through to commercial manufacturing. The companies said customers will benefit from the synergy of Solvias' expertise in chemical, analytical and solid-state development and RohnerChem's experience in scale-up and commercial scale custom synthesis of complex, small molecule fine chemicals and APIs. Financial terms of the partnership were not disclosed. ■

A Passion For Chemistry

Ferak Berlin: A Family Company with a Global Reach

Tearing Down Walls – The year 2000 marked a new beginning for family-owned Ferak Berlin GmbH. Today, the company produces fine chemicals for the life science and electronic industries under the direction of CEO Thomas Gründemann. After earning his degree in chemicals in 1992, Gründemann joined Ferak Berlin, the chemical company founded by his father in 1954 in the former West Berlin. However, despite enjoying success in the 1970s and 1980s, the company lost nearly all of its customers and employees in the 1990s after German reunification. In retrospect, Gründemann said he now regards the generational change at Ferak Berlin as a generational problem; in order to align the company's portfolio in order to meet the needs of a changed market, he had to assert himself over his father. He was successful, and he was able to establish the company as a service enterprise for organic synthesis. He was also able to increase the turnover to several million euros as well adding 25 employees to the company. Gründemann talked to Dr. Michael Reubold asked about his next goals for the company and his passion for chemistry.

Thomas Gründemann
CEO, Ferak Berlin

A worker fills a solid material in a clean room.

CHEManager: Thomas, how do you retrospectively judge the situation that led to the reconstruction of Ferak?

T. Gründemann: Ferak Berlin was established in the time of the former German Democratic Republic (GDR) as a manufacturer of laboratory chemicals and was based in West Berlin. The company maintained business relations with our customers in the GDR at that time and in other Eastern European states with an emphasis on the Soviet Union. In the mid 1980s, Ferak Berlin had over 60 employees and an annual turnover of 15 million German marks. With the reunification came the loss of most of our customers from Eastern Europe, which led to the breakdown – or one can nearly say collapse – of the company. I entered the family business, which was run by my father, in 1992 as a chemist fresh from university. Reconstruction is a typical generational change problem. As a successor of the company's founder, it was expected that I would prove my worth and go forward positively into the future. But sometimes things do not change in the way that is expected, in particular events concerned with the radical political changes at that time. Therefore the transition period from 1992 was difficult, and one which I was personally involved in up until 2000.

You then created a new company.

T. Gründemann: Yes. The follow-up regulations are really not simple for a family-owned private company. I first looked into several opinions for the possible future strategy of Ferak Berlin before I created Ferak Berlin GmbH in the year 2000 as a service partner for research projects and custom organic synthesis with me as exclusive partner. That was completely intentional to throw away the baggage from the past and to create starting point. The only leftovers from the company history were the rented business building in Berlin district Neukölln, a few remaining co-workers, a cleaning agent named Q9, which we manufactured and sold, and the business contacts we had.

How did you then continue after this new start?

T. Gründemann: Firstly, we remained with our own developed high specification cleaning agent for electronics products. This product, Ferasil, became in the course of the time a strong trademark and has since been supplemented by other branded products. In addition, I started contract research investigations for customers in the laboratory. We synthesized reagents in the laboratory on a gram scale, tested, packed and dispatched them. With time more customers came to us because they became aware of our know-how. Our clients saw that we had excellent chemists. We were a small company but one with the knowledge of the German Academy of Sciences at Berlin, which was the most important research institution in East Germany. We absolutely wanted to be successful – we had no other choice. Therefore we began looking for projects we could progress; at the time, it was just me and another colleague in development. By 2006, Ferak Berlin had four ranges: contract R&D; custom synthesis; sales of NMR analysis and expertise; and our cleaning agent business. In 2007 followed certification according to DIN ISO 9001 and today Ferak Berlin again has 25 employees, and we want our success to grow further. Production is working at full capacity, so we are really reaching our limits. We have recently financed major investments in order to develop our analytics. Now we want to invest into the development of our production, packing and storage capacities.

10 L scale-up reactor

What exactly are you planning?

T. Gründemann: We will expand into a 1,500m² area adjacent to our main building and establish three production areas as well as packing units, raw and finished material, supply and packaging items compliant with the most recent quality standards. Our "one product per campaign" strategy will be continued, both in the production and in the filling areas. With this strategy we can absolutely guarantee that cross contamination is excluded. In addition to guaranteeing industrial safety, the exclusion of all cross contamination in our business is absolutely essential. We work within the area of fine chemicals, which has very strict specifications and high purities in a niche market with high creation of value. But you must meet the highest quality standards. This is a niche market not only regarding chemistry, but also regarding the volumes.

In what quantities are these products manufactured?

T. Gründemann: We feel that from 50l to approximately 800l reactor volume is our working range. We have full permission from the authorities for this. We want to remain with reactors under 1,000l, because firstly we are located in an industrial area in Berlin and secondly it gives us a middle place in the market to be sufficiently different from those companies with capacity over 1m³. At present we have reactors from 100 to 500l. In the new production departments, we want to go to approximately 800l. This is sufficient to transfer customer projects from the laboratory scale relatively quickly into production. With this new development, we will at least double and possibly triple the existing production capacities.

However, it is not our plan to become bigger than this. That is a clear strategy, because I believe that the personal commitment to the clients and products would then suffer. As far as I am concerned, that kind of growth wouldn't be in line with what Ferak Berlin stands for. Ferak Berlin stands for excellent products whose chemistry and synthesis we understand in every last detail. The requirements of our customers regarding consistency of quality and service are time intensive to take care of. That is an important factor in defining Ferak Berlin's size and growth strategy. Some business managers nowadays have only growth in view. What is forgotten is the fact that controls and limits must also be respected.

Not just limits concerning size, but also concerning expertise.

T. Gründemann: Absolutely! I personally look at customer inquiries very closely in order to decide whether a project fits us or not. I usually answer 70% to 75% of all inquiries negatively, because I recognize that a project for some reason does not fit Ferak Berlin, for a reason such as the plant layout, the know-how, permission from the authorities, or simply because the finances are not correct. These are the classic four reasons that can lead to a refusal of project proposal. It is quite something that we can decide on which projects we take forward to work on.

However, I am quite conscious that for me this is a nice problem to have. On the other side of this philosophy is the customer who expects the highest quality, good service and an increase in value from working with Ferak. That is only fair.

We are also a member of CASID, an interest group for chemical custom synthesis in Germany. If I receive enquiries that do not fit into the Ferak Berlin portfolio or plants, then I have the option to ask for permission to pass them on to another German colleague who might be able to take on the project instead.

CASID was created in the same year as the new Ferak Berlin. How has the association developed over the last 10 years?

T. Gründemann: CASID, which is now a registered trade association, has developed to become a very successful network. In CASID, our members put the competitive situation aside in order to haveregular exchanges of experiences and recommendations. We want fine chemical manufacturing to remain in Germany, and we are all united under that goal. CASID is a Germany wide network where ideas are exchanged about regulatory matters which are of concern to all our members, e.g. GMP, Reach or the federal emissions law for the protection of the environment. It is actually very interesting to hear concepts from other members about how they have complied, at their manufacturing locations, with the federal emission protection laws.

Will the development of the new production capacity create new jobs at Ferak Berlin?

T. Gründemann: I think we are moving in the direction of employing 35 people, which is about 10 more than today. That is appropriate and viable. I still would like to know the names of every employee and see them every day. Ferak Berlin is a typical family business, and I make sure much that a certain amount humanity prevails. That is just as important to me as specialized know-how. Therefore we work only with our own trained employees and do not with borrow or hire agency personnel. Some would call it boring, I call it solid. We are a team – I can rely on my co-workers and they can rely on me.

Do you have problems finding good people?

T. Gründemann: No, I see no difficulties at all in finding outstanding qualified technical personnel. It is true at present that there is a lack of specialists, but in Berlin in the past few years many companies have reduced their personnel, and many are still doing so. Think of Schering, Jerini and Daikin. Therefore there is an enormous potential supply of specialists for research, analytics and production on the job market. Excellent chemists with unbelievable specialized know-how apply for jobs with us. Job applicants who come from a large company structure look at the family-based character of Ferak Berlin and notice that it can works well and that small firms can be completely successful.

Ferak Berlin is a small company with a large global base of clients. Where are your customers today?

T. Gründemann: We have many customers worldwide in 40 countries, in Europe, America, Asia, South America and Australia. We supply to India and Japan and have developed relations with a Chinese agency, because I believe that China offers a large potential not only for large businesses, but also for small companies such as Ferak Berlin.

For many western chemical producers, China represents not only an attractive market, but also a threat by the increasing number of new competitors. What's your take on that?

T. Gründemann: I have mixed feelings on this. We source raw materials from both India and China, and we submit these products to the strictest quality inspections. Naturally it is important to control suppliers as well, and I personally evaluate the conditions under which they produce and they supply to us. Since I am at heart and soul a chemist, I can do this. There are quite a few Asian companies who work really well, and their prices are not far from ours. Within the product quantity range up to 500 kg, in which we mainly work, the competitive situation is still quite small. But that can naturally change.

chemanager-online.com/en/tags/ferak-berlin

APIs In China

Pharma Industry Booming in Asia

© mark huls - Fotolia.com

Pharma in China – The Chinese pharmaceutical market is one of the largest due to the large size of its population. As the basis of pharmaceutical industry, the API market offers great growth opportunities for manufacturers both in-house and overseas. The API segment makes up more than 50% of the export value of China's pharmaceutical trade.

As a result, the Chinese market for APIs is rapidly growing and is estimated to witness a compound annual growth rate (CAGR) of 18% from 2010 to 2017. Ingredient suppliers in the Chinese API market will be keenly following the events in the pharmaceuticals industry, which is in the midst of integration. Apart from the sustained and rapid growth of the pharmaceuticals industry, the long-term use of multiple specialized drugs for an ageing population and the reform of the Chinese medical system have also given a shot in the arm to the Chinese API market.

As drug administrations in China put more effort into the supervision of the pharmaceutical industry, safety and environmental protection issues have become the areas of concern for the API producers. API producers in China are required to follow the guidelines such as the good manufacturing practice (GMP), which was revised by the Ministry of Health of the People's Republic of China in 2010. These manufacturers are also required to reach higher levels of standards and certifications, which are similar to the Japanese and European standards.

Chemical API Segment will Continue to Dominate the API Market in China

Chemical APIs are produced through conventional routes of synthesis. They are extensively used in many therapeutic segments such as cardiovascular, central nervous system disorder, oncology, gastrointestinal, etc. The wide usage in these applications ensures the stable growth of the chemical API market. Chemical APIs have historically dominated the global API market, and this situation is reflected in the Chinese market. China is the world's second largest producer and exporter of chemical APIs, with competitive advantage mainly in antibiotics, vitamins, antipyretics and analgesics, etc. The growth of the market is mainly driven by sustained growth in chemical drugs, especially the generic sector. Continuing patent expiries over the next few years is also considered to be a key driver for the demand of chemical APIs. By 2012, about $80 billion of patented drugs (including drugs for tumor, cardiovascular disorders and digestive problems) are expected to go off-patent, which will lead to great growth opportunities for the Chinese API market. The generic chemical API segment is considered to be well-positioned to seize these opportunities. The chemical API segment added the largest portion of sales volume with 95.1% of the total market sales volume in 2010 due to the large consumption volume of chemical drugs. Although declining in market share, the chemical API segment will continue to dominate the API market in China in the next few years. Key competitors in this segment include CSPC Pharma, NCPC, Northeast Pharmaceutical Group and other foreign and local companies.

Focus on Biotech APIs is Next Highlight of API Industry in China

Biotech APIs refer to APIs produced through the biotech routes of synthesis. Main categories of biotech APIs include amino acids, polypeptides, proteins, enzymes and others. The key product portfolio of Chinese biotech APIs includes heparin, hyaluronic acid, chondroitin sulfate, urokinase, coenzyme A and others.

Biopharmaceuticals are effective in treating certain complex diseases such as tumor, diabetes, and other immune related diseases with fewer side effects. The advancements in biotechnology and the ongoing research of biosimilars are expected to create great potential for growth of the API market globally. Comparing to chemical APIs, biotech APIs accounted for a negligible market share. However, this segment is facing a strong growth potential at a rate of 20%, which is higher than the overall API market in China. Furthermore, the generic biotech API sector is expected to grow faster than the innovative API sector. The share of the biotech API segment is expected to increase in the next few years due to the increasing focus on biological drugs.

The Chinese biotech API market is an emerging market and is also highly fragmented. Driven by the healthcare reform in China, Chinese ingredient manufacturers have made efforts for developing biotech APIs. High profit margins and competitive price of biosimilars comparing with innovative APIs also make it attractive for API companies. More leading API manufacturers are stepping into the biotech API segment in order to tap the growth potential in this market. Some of these manufacturers have the capacity to compete with foreign pharmaceutical companies in certain segments like heparin products, which are used for antithrombotic therapy. Competition in the biotech API segment is currently lower due to the complex biotech routes of synthesis.

Providing a Cost-Effective Solution to the Customers

The API market in China is highly fragmented with many participants involved. Companies located in Hebei province, Shandong province and the Northeastern areas of China are mostly large state-owned enterprises, while rising API production bases in Suzhou and Zhejiang provinces have a strong advantage in export markets. Key competitors in the Chinese API market include CSPC Pharma, NCPC, Zhejiang Medicine, Anhui BBCA Biochemical, Northeast Pharmaceutical Group. The suppliers range from CMOs (contract manufacturing organizations) of innovative and generic APIs (for example Hisun Pharmaceutical, focusing on antibiotics and antitumors), to many other suppliers which provide mainly bulk APIs with low profit margins. As more and more foreign companies established capacities in China to transfer the costs and environmental pressures, local API suppliers are facing greater competition.

Price fluctuations in 2010 have affected the revenue growth of the Chinese API market. Currently, high-performance-cost ratio products are the key strengths of Chinese API suppliers. Several China-made products have played a major part in the international market. In the long term, prices are expected to rise due to the general rise in price of raw pharmaceutical ingredients and government policies which are pushing the upgrading of the industry. Some of the pharmaceutical companies are vertically integrated to manufacture their own pharmaceutical formulations. The vertical integration is expected to help these companies to reduce costs and control the supply channel of raw materials. As the integration trend of the Chinese pharmaceutical industry is revealed, market concentration gets higher for both the generic and innovative API segment. Customers tend to build long-term relationships with ingredients suppliers. Thus, new entrants of the market are facing challenges to strive for customers.

While the potential for growth of the API market is huge, overcapacity for bulk products is greatly reducing the profitability of the API manufacturers and traders, which is mainly due to over investment. The low-margin generic API products such as vitamins and some of the antibiotics accounted for the majority of the total API market in China. For instance, the proposed capacity of vitamin C, a representative of bulk products, is expected to be more than 200 kilo tons, which will be far more than the global demand of this product. Ingredient suppliers can offset the issue of expanding production capacities by adjusting their product portfolios in line with consumer trends to maintain the profit margin. They can also achieve higher profits by focusing on the biotech API segment, which holds considerable potential, but currently accounts for a negligible share of the market.

Iris Zhao, Frost & Sullivan

▶ Contact:
Katja Feick
Frost & Sullivan
Frankfurt, Germany
Tel.: +49 69 7703343
katja.feick@frost.com
www.frost.com

chemanager-online.com/en/tags/china

A Fragmented Industry

Peter Pollak on the World of Fine Chemicals

Overview – In his book "Fine Chemicals – The Industry and the Business," Dr. Peter Pollak provides a comprehensive view on one of the most challenging segments of the modern chemical industry, and a practical guide for succeeding in the multibillion dollar fine chemicals business. The second edition, which was published by Wiley in May, takes developments in the field since the first edition was written into consideration, including substantial updating of facts and figures; new chapters on M&A and biosimilars; and a discussion of the offer/demand development of the modern pharmaceutical fine chemicals industry. Before becoming a consultant in fine chemicals business and a board member of several fine chemical companies, Pollak spent more than 30 years at Lonza. CHEManager Europe asked him about the development and the current and future challenges of the global fine chemicals industry.

Dr. Peter Pollak
Fine Chemical Business Consultant

© Maxim_Kazmin - Fotolia.com

CHEManager Europe: Dr. Pollak, you write in your book that all fine chemicals, in general, are used to make specialty chemicals. Is there a more detailed definition that helps to understand the importance and value of fine chemicals?

P. Pollak: Fine chemicals are complex, single, pure chemical substances. They are produced in limited quantities – up to about 1,000 tons/year – in multipurpose plants by multistep batch chemical or biotechnological processes. They are described by exacting specifications, used for further processing within the chemical industry and sold for more than $10 per kilo.

The class of fine chemicals is subdivided on the basis of the added value – building blocks, advanced intermediates or active ingredients – and the type of business transaction, namely standard or exclusive products.

The pharmaceutical industry, which is the largest user of fine chemicals, distinguishes between drug substance, which is the active ingredient, a fine chemical, and drug product, which is the formulated, finished drug, a specialty.

The fine chemicals industry is very fragmented …

P. Pollak: Yes; globally, there are 2,000–3,000 fine chemical companies, extending from small, "garage-type" outfits in China making just one product, all the way to the big, diversified companies. Among the top 20, 17 are divisions of large chemical or pharmaceutical companies like Albemarle; BASF; and Boehringer-Ingelheim, and there are only three pure players. In terms of geography, nine of the top 20 are located in Europe, which is recognized as the cradle of the fine chemical industry. An example in case is the world's No. 1 company, Lonza, headquartered in Switzerland. The second largest geographic area is Asia, housing seven of the top 20. With four large companies, the U.S. ranks last. The combined revenues of the top 20 reached about $10 billion in 2009.

Table 1: Definition of Fine Chemicals

Commodities	Fine chemicals	Specialities
Single pure chemical substances …	Single pure chemicals substances …	Mixtures
Produced in dedicated plants	Produced in multi-purpose plants	Formulated
High volume/low price	Low vol. (< 1000 mtpa) high price (> $10/kg)	Undifferentiated
Many applications	Few applications	Undifferentiated
Sold on specifications	Sold on specifications "what they are"	Sold on performance "what they can do"

Source: Peter Pollak, Fine Chemicals – The Industry and the Business, 2nd, rev. edition

Traditionally a European and North American business, the fine chemicals industry is globalizing at a fast pace. What are the driving forces behind this globalization?

P. Pollak: In the fine chemical industry, globalization mainly refers to the impressive foray of Asian, especially Chinese and Indian companies. In simple terms, their success is based on their "high skill/low cost/bright future" competitive advantage. "High skill" not only refers to the education of managers and scientists (not to mention the sheer number of university graduates), but also to the quality of the fine chemical plants, corporate governance, safety, health and environment standards, regulatory compliance, etc.

Auditors from the leading Western pharmaceutical companies agree that the top tier Chindian (Chinese and Indian) companies' standards are in line with those of their Western competitors. "Low cost" not only means low wages for the plant operators, but also low construction costs of Chindian fine chemical plants.

A dramatic example is the cost of the pivotal piece of equipment of every multipurpose fine chemical plant, the reaction vessel. The unit cost for a fully installed reactor ranges from $10 milllion/m^3 for a reactor installed in a Western Big Pharma company, to $1 milllion/m^3 for a Western plant, and $0.1 million/m^3 in a Chindian plant.

"Bright future" means that the demand for the two main outlets for fine chemicals, namely pharmaceuticals and agrochemicals, enjoy "double digit percent annual growth rates" in the Eastern hemisphere, whereas it has decreased to "low single digit percent annual growth rates" in the Western part of the world. The main beneficiaries of this surging demand obviously will be the domestic suppliers in Asia.

Most fine chemicals are produced captively or under an exclusive contract for a single customer, especially when it comes to fine chemicals used for pharmaceuticals. What kind of pressure does the consolidation of the customer base (e.g. pharma) put on fine chemical companies?

P. Pollak: The increasing purchasing power of the life science industry in general and Big Pharma in particular leads to more and more stringent clauses in the supply contracts for fine chemicals.

These comprise not only the pricing, "cost transparency" and prefixed yearly "cost improvements" have become almost standard elements, but are extended to currency clauses – a particular problem for the Swiss industry, suffering from a grossly overvalued franc –, flexibility regarding production volumes and timing of production campaigns, obligation to source raw materials from a given supplier, share know-how with competitors, etc.

The pharmaceutical industry itself is under pressure by governmental drug price reductions, patent expirations and low innovation rates. What does that mean for the fine chemical producers and custom manufacturing organizations?

P. Pollak: Most of these developments have an unfavorable effect both for the fine chemical industry in general and custom manufacturers in particular. Although the incidence of the cost of the fine chemical used for a particular pharmaceutical is small, typically less than 5%, price reductions on the finished drug invariably lead to requests for price concessions. More than $100 billion of drug sales revenues will be affected by patent expirations over the next few years. When proprietary drugs plunge over the patent cliff and become generic, prices start to collapse immediately and typically end up at a level of about 20% of the original price of the APIs affected.

Consequently, Western suppliers are driven out of business in many cases. New drug launches have fallen from an all time high of 51 in 1997 to about 20 per year at present. Thus, not even all of the top 20 pharma companies manage to launch one new product per year. Moreover, as many new drugs either are me-too drugs, showing only marginal improvements, or treat rare diseases, also the volume requirements decrease. The unpleasant consequences for the CMOs are fewer business opportunities, both quantitatively and qualitatively.

There is, however, also a piece of good news. As part of restructuring programs implemented by most life science companies, the axiom of captive manufacture of fine chemicals being a core activity is abandoned. The practical implications are plant divestments or even shutdowns – and more outsourcing, both of drug substance and product. The chips are out as to which extent the increase in outsourcing will compensate the negative developments mentioned.

Pfizer, with sales of $50 billion in 2009 is the world's largest pharma company. Its top selling product, with a revenue of $11.4 billion, is the cholesterol-lowering agent Lipitor. Patent expiries in Canada and Spain already caused a sales reduction of 21% in Q2 2011. The situation will worsen when generic versions will also be on sale in the U.S. as of November. According to Bloomberg, Pfizer will suffer from patent expiry of 18 more drugs by 2015. They generated 60% of revenues in 2009!

What is your estimate for the size of the fine chemicals market in the future depending on different growth scenarios?

Continues Page 14 ▶

Flexibility, Internationality and Know-how

Industry Service: Expectations on Technical Service Providers Growing

Complexity – Bilfinger Berger Industrial Services (BIS) offers its process industry customers complex services for the entire plant life cycle. As an independent subgroup of Bilfinger Berger with 28,000 employees, the company earned €2.9 billion in 2010. And all signs are pointing to further growth. By focusing on the core markets of the process industry – such as chemicals and petrochemicals, pharma, food, refineries and power stations – BIS is able to meet the high demands of its customers. CHEManager Europe asked Dr. Joachim Kreysing, executive vice president of the BIS Group, about current and future challenges for technical service providers.

CHEManger Europe: At the Bilfinger Berger Industrial Services Group all signs are pointing to continued growth. What role is the chemical industry playing in this respect?

J. Kreysing: A very important one. The BIS Group generates a large proportion of its revenues from business with companies in the chemical industry. In fact, it is one of the most important sectors for us. More than 80 BIS companies provide services for companies in the chemical industry. As the European market leader in industrial services for the process industry, we are very firmly positioned in this key sector within the German economy.

The sector is exposed to heavy global competition. In what way does this affect you as a provider of services?

J. Kreysing: Our customers have very high expectations and are increasingly seeking service providers who are also strategic partners. As the production facilities are mostly bespoke, it is necessary to sit down with the customer to develop individual solutions which go beyond a mere checklist of standardised services and which also entail consulting and the implementation of new processes. This may, for example, involve drawing up a road map to define how the entire service system for a company is to be developed.

What demands does the chemical industry make on maintenance companies?

J. Kreysing: As economic success hinges materially on the degree of efficiency in maintenance activities, the foremost imperative is to obtain an optimum balance between plant availability, maintenance times and cost.

At the same time, the market for turnaround services is looking for general contractors able to handle planning and overall coordination in addition to execution of the actual activities. Companies operating internationally seek service providers who likewise have an international outlook.

These are very diverse requirements. What form does a specific partnership with customers take?

J. Kreysing: Depending on the customer's specific requirements and objectives, the BIS Group offers various partnership models. The forms that these contracts may take entail individual, outline, and main contracts as well as full-service maintenance and general contractor contracts. With these forms of partnership, the scope of the activities covered by the BIS Group is growing all the time. This also applies to the extent to which we are involved in strategic matters and assume responsibility for maintenance as well as project execution.

Dr. Joachim Kreysing
Executive VP, BIS Group

Regardless of the type of partnership, agreements are entered into on an individual basis and adjusted in the light of the customer's requirements. In the case of customers with whom we have entered into full-service contracts, we assume complete responsibility for maintenance. With this form of partnership, we work with long-term contracts of a minimum term of five years. This provides the customer with a secure basis while we, for our part, are motivated to maintain the quality of service at a high level, boost plant availability and thus contribute to the customer's productivity. In fact, we go so far as to develop new contracts models with the customer including, for example, such elements as bonuses for the avoidance of non-scheduled repairs and down times.

With respect to turnarounds, customers are also increasingly expecting us to handle long-term planning as well as the overall coordination of the execution phase and ensuing evaluation of the experience gained as input for future turnarounds. These are very demanding projects as the customer expects to receive a more reliable base for planning costs and particularly also schedule compliance in tandem with high standards in work safety and quality assurance. We have a very strong international position in large turnarounds as we not only have the experience but also the necessary capacity within the group.

You introduced the BICEPS program some time ago. What precisely is it?

J. Kreysing: In the chemical industry, it is crucial for data on staff medical checkups and training to be kept up to date and monitored on an ongoing basis. The Bilfinger Berger Industrial Services Certification E-Management Programme, or BICEPS for short, is a computer-aided tool allowing the company to manage and monitor this data. Employee profiles are created for each activity. The web-based tool manages and monitors due dates, checkup dates and training. At the same time, it prints out safety passes in various different formats. For those in charge of HSEQ or "health, safety, environment, quality," to give it its full name, this is an enormous help and greatly simplifies their activities.

The chemical industry has an international footprint; not only large companies are acting on a global basis but increasingly also SMEs. What role is the international network of BIS companies playing in this respect?

J. Kreysing: The network of BIS companies is very valuable to us. Our international customers frequently want to implement models that we have established with them in a particular country at other sites as well. Via the BIS companies located in these countries, we have from the outset local expertise that can be perfectly tailored to meet these requirements. Customers are able to benefit substantially from this – not least of all because it is possible to initiate and implement new projects with shorter startup times.

Other aspects include flexibility and the willingness to provide services. In the case of large turnarounds, for example, we are able to deploy BIS staff from neighbouring locations and thus provide the necessary resources.

Our central corporate units also play a key role in addressing our customers' international requirements by regularly working on domestic and international consulting projects and performing maintenance analyses. These give rise to specific proposals for maintenance strategies and execution.

What do you consider the main challenges to be and how is the BIS Group responding to these?

J. Kreysing: Flexibility, an international outlook and consistently up-to-date expertise form the basis for future success. As far as the customer-vendor relationship is concerned, we will continue to see a move away from the conventional links in favor of partnership-based models in which customers request strategic input from service providers and assign responsibility to them.

In turnaround business in particular, we expect local management activities to increasingly evolve into cross-plant structures. This means that it will be necessary to assign specialists to multiple plants in the future. What is required will be general contractors able to coordinate the entire cycle from the planning phase right through to formal completion of the project. In addition, internationally active customers are seeking strategic service partners which also have an international base. We as a company are addressing these trends by enhancing our services and strengthening our international orientation.

chemanager-online.com/en/tags/industrialservices

Fighting Counterfeits

Enhanced Safety for Pharmaceutical Packaging

Protection – The seamless documentation of supply chains and the ruling out of counterfeit products as far as possible are measures that serve to protect producers as well as patients. These functions are assigned to one- and two-dimensional codes with which pharmaceutical manufacturers in an increasing number of countries are legally required to mark their products. However, that is just one step. Such an identification system must function across national borders and be adaptable to meet local requirements. A wide variety of peripheral equipment has to be integrated into an overall system, data processed, and existing machines suitably upgraded.

In several countries such as India, China, Brazil and Turkey it already applies; in others such as Russia, Spain and the U.S., it is in the pipeline: legislation governing the unique marking of the smallest unit of sale of pharmaceutical products with a code.

Problematic is the fact that the laws vary from country to country. While straightforward "French coding" by simply printing and verifying the code without data archiving suffices in France, in Turkey, for example, the verified codes have to be transmitted to a government database. The form of code also differs. In some cases, a simple barcode (Code 128) depicting the data as a binary symbol is sufficient, whereas a data matrix code or 2D code encodes detailed information such as the product identification number, serial number, batch number and expiry date (YYMMDD) in a pattern of dots.

To ensure that coding is carried out properly, peripheral equipment such as camera systems and printers have to be purchased, installed in new and/or existing lines, integrated in a line database, and linked to the manufacturer's in-house IT infrastructure. This is a complex task that speaks in favor of an integrated solution with all components and services provided by a turnkey supplier. Moreover, a solution based on a system that not only meets the requirement of marking the smallest unit of sale, but also offers benefits in terms of efficiency of the complete packaging process.

Competence from a Single Source

Track & Trace by Uhlmann is a joint development with VisioTec, Uhlmann's center of excellence for pharmaceutical inspection and printing systems. Track & Trace is implemented in three steps: Uhlmann VisioTec first provides the peripheral equipment such a laser or ink-jet printer and inspection systems for the verification of the codes and competently integrates these into the packaging lines. The second step involves the linking to a line database. In the third step, the line data are transferred to a higher ranking system of the pharmaceutical manufacturer, the site server. Uhlmann has its own site software solution or cooperates closely with IT specialists that have established software systems for such applications. These systems also take over the processing of the data for the company network and the transfer of data to the authorities. To ensure the ideal integrated solution from the packaging line to the internal ERP systems, Uhlmann maintains overall responsibility for the project and is the sole contact partner for the customer. This is the case no matter whether the system is integrated in an Uhlmann line or in packaging lines of other machine manufacturers.

Parent-Child Relationship

Track & Trace by Uhlmann works on the principle of parent-child relationship. Every element is marked with a code from the smallest to the largest packaging unit. A tracking database supplies the data to higher ranking systems and links the information for maximum pharmaceutical reliability.

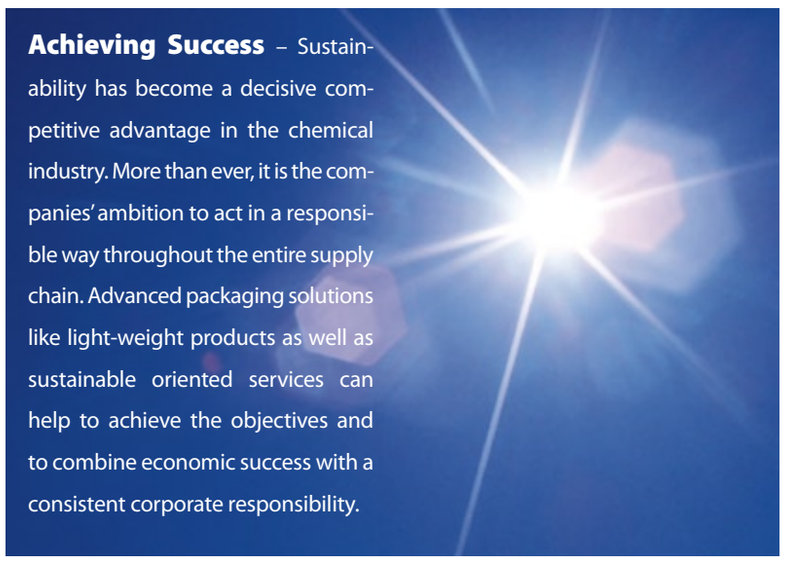
▶ Contact:
Oliver Naucke
Uhlmann Pac-Systeme GmbH & Co. KG
Laupheim, Germany
Tel.: +49 7392 702 8277
naucke.o@uhlmann.de
www.uhlmann.de

chemanager-online.com/en/tags/packaging

Track and trace legislation worldwide

Let There Be Light!

How Industrial Packaging Can Boost Sustainability Measures



Achieving Success – Sustainability has become a decisive competitive advantage in the chemical industry. More than ever, it is the companies' ambition to act in a responsible way throughout the entire supply chain. Advanced packaging solutions like light-weight products as well as sustainable oriented services can help to achieve the objectives and to combine economic success with a consistent corporate responsibility.

As a fast moving business sector, the chemical industry faces several challenges every day. Especially as chemical companies bear a major responsibility in terms of sustainability – to both society and the environment. Therefore, many of the enterprises have already implemented sustainability initiatives in their companies to reduce the environmental impact and to generally act in a more responsible way.

However, activities in the field of sustainability need to be looked from a holistic perspective. On the one hand, there are usual internal processes that should be optimized. This includes measures as simple as the reduction of electricity and gas consumption, the responsible use or reuse of water as well as a stringent waste separation. But sustainability measures need to contain external processes as well – through partners, vendors and service providers that support the companies' sustainable approach.

Focus on the Entire Supply Chain

For companies in the chemical industry, it is increasingly important to cooperate with suppliers who are also committed to a sustainable approach in order to achieve their own sustainable goals. This requires the involvement of the entire supply chain – from a fuel-efficient route planning through to sustainable industrial packaging solutions. Especially because advanced packaging designs do not only ensure a safe and reliable transport of sensitive goods. They can furthermore help companies to combine ecological with economical targets.

As Companies Need It – Fit for Purpose

Often used and proven as reliable packaging solutions for the transport of sensitive or dangerous filling goods are intermediate bulk containers (IBCs). A manufacturer who offers a comprehensive portfolio of IBC solutions for the most

Dr. Clemens Willée
CEO, Mauser Holding

diverse requirements is the Mauser Group. Their composite IBCs fulfil international packaging regulations and are blow-molded from UV-stabilized polyethylene of high molecular weight and density. This enables an excellent chemical compatibility and makes the bottle to be used for a broad range of filling goods. IBCs have the advantage of being produced with a modular design and a variety of accessories as well as material choices. This allows the adaption of individual packaging solutions meeting different customer demands without overdesigning. There are, for instance, packaging solutions available that are comprised of an external layer of permanent antistatic compound. This prevents the solution of becoming electrostatically charged. Other IBC solutions reflect sunlight and thereby help to control temperature levels inside the container in order to avoid chemical reactions. Several additional specifications and options make IBCs the first choice for the chemical industry. Also, new materials and comprehensive reconditioning services support companies in the chemicals in pursuing their goals in terms of sustainability.

Reconditioning: A Clean Business

The reusability of industrial packaging solutions is gathering speed. Today, vendors offer comprehensive programs providing customers with new products and additionally remanufactured, reconditioned and laundered packaging solutions. Through making use of reconditioning services, companies in the chemical industry contribute to decrease the volume of raw materials – without having any quality loss in packaging. By doing so, customers are able to act in an ecological way and underline their own sustainable activities. To secure the greatest possible outcome, companies should attach importance to the partners' presence around the globe and verify whether the supplier is able to offer full service reconditioning services with short distances worldwide.

Less Is More

The Mauser Group is continuously searching for innovative solutions. With its sustainable business approach, it is able to manage the entire packaging lifecycle in a sustainable way, comprising the complete supply chain – from production to recollection to recycling. Latest developments in the industrial packaging industry show the potential of sustainable solutions – e.g. in the field of bioplastics. Mauser already produced prototypes of IBC pallet components or blow-molded bottles for the usage in the agrochemical industry. Even if the area of bioplastics for industrial packaging solutions still is in an early stage and the availability of material as well as the material costs make it difficult to issue an accurate forecast – the innovative potential is huge and implies an interesting option especially for customer-specific developments in the near future.

Many developments demonstrate that sustainable solutions are already real today. Thanks to the reduction of materials, Mauser is already able to produce light-weight packaging solutions, maintaining the customary high-quality accompanied by a positive influence on the environmental impact. For example, in the recent past, the company realized weight saving up to 10% through new product design or the use of improved materials. When using light-weight solutions, companies not only support a resource-sparing production of packaging solutions. They furthermore benefit from a lower fuel consumption and transportation costs.

Conclusion

Sustainability is not just a symbol of good deeds anymore. It is a philosophy that needs to be lived within a company. Advanced packaging solutions can help to organize supply chains more sustainably and to expedite the company's initiatives. By cooperating with an experienced partner that is able to attest his achievements and objectives through reports and analysis, companies in the chemical industry can gain a competitive advantage and combine social responsibility with economic success.

▶ Contact:
Dr. Clemens Willée
Mauser Holding GmbH
Brühl, Germany
Tel.: +49 2232 78 1000
info@mausergroup.com
www.mausergroup.com

chemanager-online.com/en/tags/packaging

Pharma

An in-depth look at the future of pharma

Pages 12 – 13

API Sourcing

Is Asia the only option for the future?

Page 15

Short Interviews

Read what industry leaders have to say about the latest trends

Pages 16 – 18

Ei Gude, Wie?*

The CPhI Returns to Frankfurt

Tailor-made – Almost 30,000 people visited the CPhI in Paris last year – that's equivalent to the population of an averaged-sized town. While the show has grown and grown since its inception in 1990, it has also faced its fair share of criticism from the industry regarding its size – something the its directors say reflects industry growth. The show's brand directors Annemieke Timmers (CPhI) and Haf Cennydd (ICSE, P-MEC & BioPh) are therefore always on the look-out for new ways to better connect with the industry's needs and tailoring the show accordingly. Brandi Schuster spoke with them ahead of this year's show in Frankfurt, to take place Oct. 25–27.

Haf Cennydd
Brand director, ICSE, P-MEC and BioPh

Annemieke Timmers
Brand director, CPhI

CHEManager Europe: What trends have you picked up on in the industry since last year's show in Paris?

A. Timmers: From our additions of the new InnoPack event and the LabWorld Pavilion within P-MEC, it is clear that there are areas of the market with new or transitioning demands for resources. For instance, InnoPack will address the increased need for innovative packaging concepts in the global pharma market, including resources and solutions for the production of blisters; blow-molded plastics; ampules and vials; caps and closures; tubes and glass; bottles; pouches; strip packs; and more.

H. Cennydd: Similarly, the LabWorld Pavilion, which debuts at P-MEC Europe, reflects the significant diversification seen in global exhibitor demographics throughout the P-MEC events by offering resources beyond the "traditional" large-scale capital machinery with which the event has become associated. The LabWorld Pavilion will effectively offer high technology laboratory solutions such as instrumental analysis, measuring and testing technologies, materials testing, quality control and laboratory equipment that cater for smaller scale lab environments.

While most chemical companies have posted positive quarterly results, many pharma companies have seen a drop. Will this dynamic have any effect on the show? How are this year's exhibitor numbers looking compared to 2010?

A. Timmers: We are thankful to say that this dynamic does not appear to have directly affected the show. 2010 was a record year in Paris and as we approach 2011 in Frankfurt, there is once again growth across all of the events.

How have the parallel shows ICSE, P-MEC & BioPh been developing? What can visitors expect this year?

H. Cennydd: Each event is constantly changing to cater specifically to its target market. As such, the brands have all experienced development in their own right. ICSE has evolved through the expansion of the zoning that was introduced last year in Paris. For 2011, the General and CRO-Clinical Trials zones will return to ICSE and will be joined by additional zones to highlight New Exhibitors, USA Exhibitors, and Logistics and Supply Chain. The new InnoPack event was borne out of the Packaging Zone that successfully debuted in 2010 as part of ICSE, while P-MEC Europe will introduce the LabWorld Pavilion in response to the increasing demand for small scale laboratory instruments and resources. Finally, BioPh has transitioned away from a standalone event and into zones within CPhI and ICSE to more effectively offer visitors resources for a wide range of specialized biopharm areas such as bioelectronics, diagnostics and technology services.

Two new zones have been added to the Frankfurt show – generic APIs and finished dosage. What led to this? Will there be any new elements to this year's show?

A. Timmers: The zoning format was introduced in Paris last year to more effectively facilitate navigation of the events and it received exceptional feedback from both exhibitors and attendees. As we carried the zoning format over into the 2011 show, we evaluated ways to expand the usefulness of this format for visitors. Pre-show registration patterns consistently show that resources for both APIs and finished dosage are two of the biggest demands from our visitors, which is no surprise, as CPhI's primary focus remains the pharmaceutical ingredients market.

Also new this year are the Lunchtime Learning Sessions presented by CPhI Conferences, comprising six different workshops across the three days. The series features a lunch break in between the two daily sessions to further facilitate networking and the creation of new business connections for registered attendees. Also exciting are some of the new digital offerings for pre-show planning that include the "Exhibitor Invites" feature for exhibitors to invite targeted attendees to their booth, as well as the "Who's Attending" feature for visitors to see who is onsite from exhibiting companies and plan meetings. The social media aspect of the show has also been expanded to offer up to date information from the show floor, as well as to maximize networking onsite at the events, and facilitate connections that will allow for networking and expanded business exposure even after the events close.

Conferences like the Pharma Chem-Outsourcing in New Jersey are gaining in popularity within the industry because of the familiar atmosphere. The CPhI, on the other hand, is one of the largest events in the industry; what steps are you taking to make it more personal for visitors and exhibitors?

H. Cennydd: As such a large exhibition, it is important that we do not lose the personal connection to our client base. A large part of this is listening to feedback and paying attention to market trends that affect our exhibitors and visitors. CPhI, ICSE, P-MEC Europe and InnoPack have all been tailored around research and feedback from our customer base and even in such a large-scale environment, we feel that the events are still able to provide a unique experience to each visitor. Our core focus on networking events, whether educational or purely social, allows for guests to maximize their time onsite and foster existing business relationships, while also making new business connections. Features like Zoning allow visitors to schedule their own agenda while onsite and easily locate exhibitors who provide targeted solutions for their needs within the different sectors of the Pharma industry.

What are your expectations for the Frankfurt show?

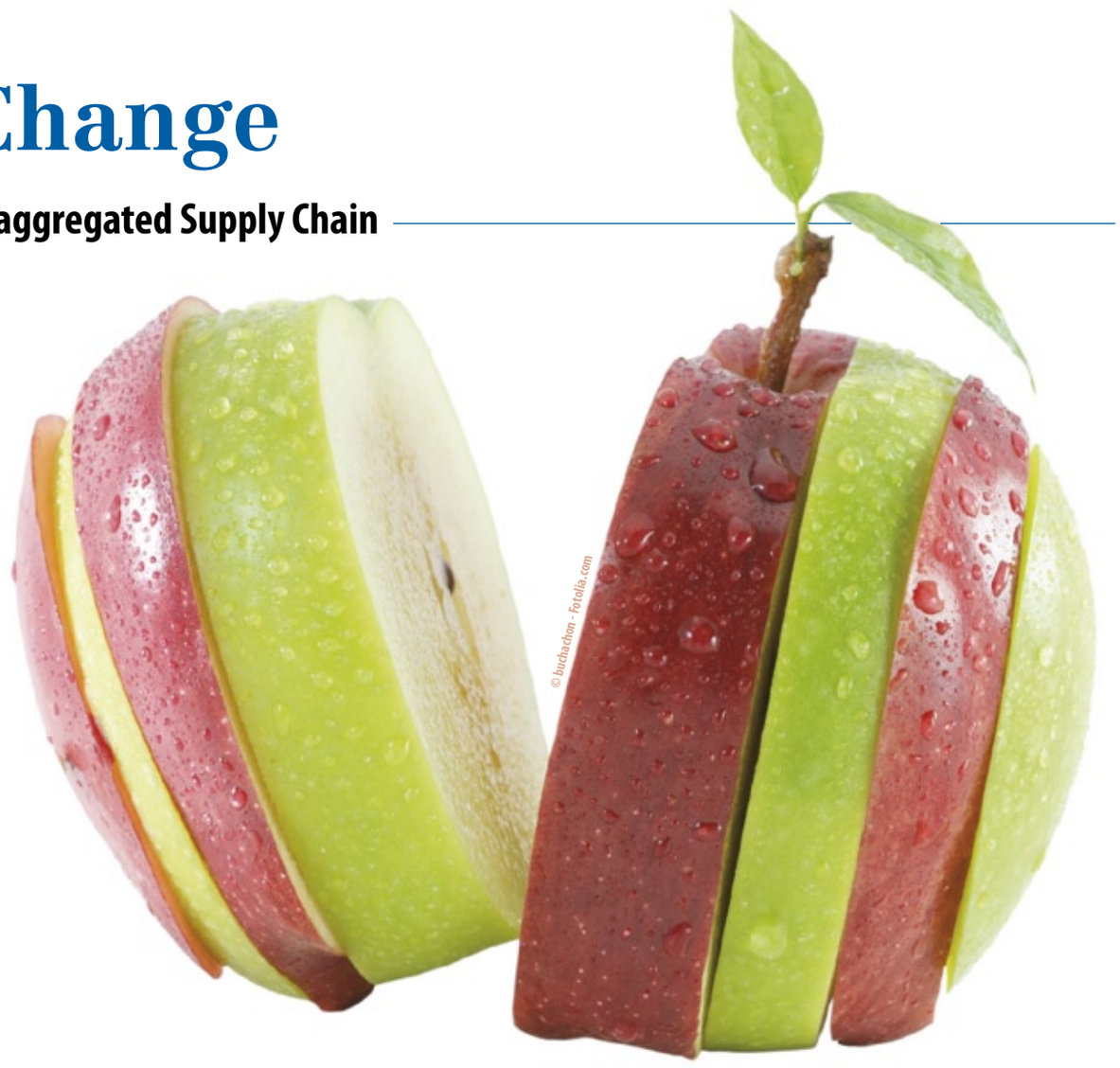
H. Cennydd: The last time the events were held in Frankfurt was in 2008, and we had extremely positive feedback from visitors. The venue itself is located in a central and vibrant pharmaceuticals business market that provides optimum accessibility for both local and global visitors. We are pleased to return to Frankfurt for the 2011 editions of CPhI Worldwide, ICSE, P-MEC Europe and InnoPack with a positive outlook. Last year's events in Paris hosted record attendance of 28,897 unique visitors, and we are excited to have expectations of another record year in Frankfurt.

*Frankfurter dialect for "How are you?"

chemanager-online.com/en/tags/cphi

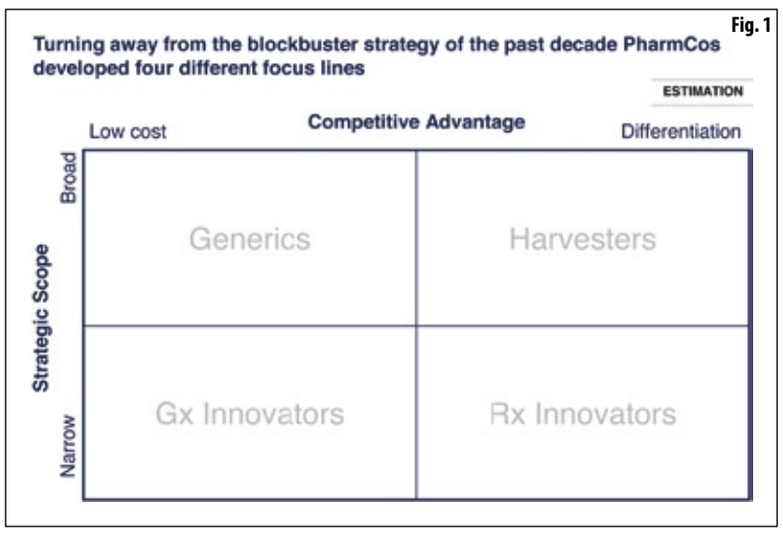
Game Change

Pharma's Future with a Disaggregated Supply Chain



New Rules –The game has changed for the global pharmaceutical industry. Numerous forces are shaping this new pharmaceutical era: The rise of emerging markets, increasing price pressure and expiring patents are just some of the factors forcing pharmaceutical companies to change the way they operate and how they manage their value chain. "Drug Supply 2.0: How to manage a disaggregated pharmaceutical supply chain" is a study by Camelot Management Consultants, the ESB Business School Reutlingen and the S.P. Jain Institute of Management and Research (SPJIMR) Mumbai that examines how companies are responding to the changed environment and looks at the growing role of third-party suppliers in the pharmaceutical business. The interviewed companies are no newcomers to the field: 88 % of the companies look back on more than 10 years of experience in sourcing supply chain services and already manage on average a portfolio of 214 suppliers. They count among the sector's forerunners.

Fig. 1



Geographic Shift and Supply Chains

Although traditional markets account for the bulk of sales, "pharmerging" markets will outpace traditional markets in terms of growth by 2013. Given the environmental forces at play, pharmaceutical companies have no alternative but to make striking changes to their supply chains. A closer cooperation with contract manufacturers or R&D providers is the chosen option. This is not only the easiest way to partner in new and uncertain markets, it also enables them to manage increasing price pressures arising from health care reforms, patent expiry and the success of generics.

Each of the four new strategic business models adopted by pharmaceutical business units – Harvesters, Rx Innovators, Gx Innovators and Branded Generics (fig. 1) – requires stronger partnerships with third-party suppliers to be formed to guarantee success. According to the experts interviewed, the potential for doing so is huge: Up to 75 % of production volume could be reallocated to third-party manufacturing. Yet there are hurdles that need to be overcome. Managing a disaggregated value chain involving a growing number of third-party providers is a different game than managing own sites. More extensive and new forms of information exchange beyond the own company´s boundaries will be necessary to ensure productive planning.

This is increasing the pressure on supply chain management to create processes to steer this new virtual network, reducing the threats seen in know-how transfer, internal change process and increasing administrational costs. On a positive note: while the majority of companies still primarily let the manufacturing organization make supply chain disaggregation decisions, already one-third of companies have turned this into a boardroom decision.

Reshaping The Supply Chain

Abandoning the single minded blockbuster mindset, pharmaceutical companies have been forced to review their business plans and reconsider new business models as well as how they allocate their capital. Contract manufacturing organizations (CMOs) play a large role in the business models that are evolving. CMOs are increasingly being considered strategic partners, responsible for greater amounts of the portfolio volume, and less as step-in organizations to smooth out manufacturing peaks. This view is supported by this study's participating companies, which believe that this trend will gain even more traction over the next five years.

Most pharmaceutical companies already outsource activities such as clinical trials, API production or logistics to third-party suppliers. Over the next five years, pharmaceutical companies are likely to become more emboldened and will start examining all their technologies and business processes for outsourcing opportunities, according to the companies interviewed. When this happens, contract service providers will have made the jump from service to strategic partner.

Based on the experience and roadmap of other industries like automotive and electronics, pharmaceutical companies are likely to make this change in three phases:

Phase 1: Early wins

In this phase companies focus on low-risk support functions such as finance and accounting, IT and HR as well as low-risk R&D functions such as clinical development and data management.

Phase 2: Minimal risk move

In the second phase, companies are prepared to move out of their comfort zone and start outsourcing contract service functions such as bulk drug manufacturing and packaging, API production and 3PL. They are also likely to consider the outsourcing of R&D activities including bio-informatics, analytic services and Phase III clinical trials. Other functions like the sales force are also outsourced during this phase. Companies are encouraged by the significant bottom-line impact and variabilisation of their cost base resulting from this outsourcing and spurred by the emerging vendor base already built-up by some big pharmaceutical companies.

Phase 3: Collaboration

In the third phase, companies start collaborating with third-party suppliers, seeing them more and more as trusted strategic partners. Outsourcing leaders will sign contract partnership deals involving new product development, full single/multi-market supply as well as direct to pharmacy by 3PL. At this stage, R&D outsourcing involves lead generation and optimization. Increasingly, support functions such as planning and data services will also be outsourced.

The Rise of the 'Pharmerging 17'

The second major pressure front forcing pharmaceutical companies to alter their supply chains radically is the explosive and continuing growth of the emerging markets. While traditional markets are growing at a steady single-digit level, the "pharmerging markets" promise growth of up to 15 % over the next few years. These emerging pharmaceutical markets are generally divided into three tiers:

- Tier 1: China
- Tier 2: Brazil, Russia and India
- Tier 3: Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, South Africa, Thailand, Indonesia, Romania, Egypt, Pakistan and the Ukraine

The sheer size alone of the population in the tier 1 and tier 2 markets creates tantalizing opportunities for pharmaceutical companies that manage to establish themselves in these countries. In addition China still provides a good hub to enter Africa beyond tier 3 markets due to China's good relationships with markets in central Africa.

Established companies should by-pass the tried-and-tested business models that they use in the traditional triad markets North America, Europe and Japan and opt for new models to address the emerging markets. Given each country's unique market dynamics, health care system, political and regulatory environment, experience in dealing with established western players and general ways of doing business there is no generic blueprint for success.

Navigating the Global Supplier Landscape

The local nature of contract research outsourcing (CRO) and CMOs makes them ideal partners for entering these unchartered and unfamiliar markets. Partnering with CROs and CMOs will make it easier for established pharmaceutical companies to get a toehold in these regions. In some respect, pharmaceutical companies will have no other choice: Stricter import regulations, for instance, will force pharmaceutical companies to either invest directly or enter partnerships with local players if they wish to be active in the market. Business constraints also encourage pharmaceutical companies to get involved in joint ventures, R&D partnerships, strategic business collaborations, and to gain more experience in out-licensing and outsourcing. Lower per capita health care spending, for example, means companies must offer products at a lower price. To accomplish this without exposing profits to risk, bigger amounts of the supply chain will need to be shifted to local partners.

For many companies, it just makes good business sense to have strong partners on the ground who understand the local market and who can quickly respond to changing conditions. This is how the needs of local customers can be met. Other companies will prefer to collaborate closely with hospitals and medical centers in specific regions.

Combined or full service providers like CRAMS (contract research and manufacturing) will continue to provide the highest growth opportunity. Some of the bigger contract service providers could start to lead the global market concentration. Also private equity firms could start to concentrate the low end to build competitive full service suppliers.

The New Strategic Pharmaceutical Business Models

Tectonic shifts in the pharmaceutical industry have compelled companies to take drastic action in order to secure their long-term survival. With the blockbuster strategy of the past decade losing currency, pharmaceutical companies have increasingly been branching out into new business areas. The business segment strategies of big pharma of the future are more versatile than as seen in the past:

Big pharma – referring to top 20 pharma by sales – have redefined their strategy mainly by differentiating into four business models, which we can be segmented in the clusters "Harvesters", "Rx Innovators", "Gx Innovators", and "Branded Generics." These business models are far more diversified than the old blockbuster one and open up new opportunities, especially for companies that can rely on no strong pipeline.

Put simply, Harvesters expand their portfolio by making a broad range of highly differentiated products for new markets, Rx Innovators divest assets to focus on developing new drugs, Gx Innovators add value to expired patents with their low-cost and narrow focus, and Branded Generics produce a broad range of products at low cost (fig. 1).

The Road Ahead

Turning away from the blockbuster business model, pharmaceutical companies are concentrating on their core competences and increasingly exploring avenues to shift product volume to third-party manufacturing to keep their own assets low. The expected cost reduction from disaggregating certain supply chains amounts to 43 % on average COGS basis, providing an exceptionally good reason for hesitant pharmaceutical companies to wholeheartedly embrace this trend.

The products and functional services most pharmaceutical companies are prepared to source from a third-party provider within the next five years are still limited, in terms of their cost saving potential as well as their complexity. As a whole, pharmaceutical companies are just starting to jointly develop

Continues Page 13 ▶

Breaking Taboos

Pharma Must Make Big Changes to Survive

Evolve for Survival – Patent cliff, the rise of "pharmerging" markets: These are just a few of the challenges the global pharmaceutical industry is facing. In order to ward off billions of dollars in losses, pharma companies will have to redesign their supply chains and become less squeamish about outsourcing more and more elements of their businesses. These issues were highlighted in the recent study "Drug Supply 2.0" conducted by the ESB Business School, Camelot Management Consultants and the S.P. Jain Institute of Management and Research (SPJIMR) Mumbai. Brandi Schuster spoke with Camelot's pharma experts Ulrich Korneck and Michael Jarosch about the results of the study.

Michael Jarosch
Partner and pharma expert, Camelot Management Consultants

Ulrich Korneck
Expert for contract manufacturing and external supply, Camelot Management Consultants

CHEManager Europe: The study shows that Western pharma companies have to cooperate with contract manufacturers and/or R&D providers in order to compete with pharmerging markets. Although all signs have been pointing to this kind of shift in the market, Big Pharma has been very slow to outsource. Why?

U. Korneck: In the past, the main business model in the pharma industry was about blockbusters. With such high-value products – more than $1 billion in sales per product – pharma companies were very adamant about protecting their intellectual property, keeping most of their knowledge and processes in house. But now there is pressure to reduce costs and blockbusters are going off patent, practically invalidating the blockbuster business model.

Did the industry just not see the signs or did they choose to ignore them and trudge on with the blockbuster business model?

M. Jarosch: Yes, they did see the signs, but they also have an existing asset footprint that needs to be leveraged. It takes time to sell assets to contract manufacturing organizations (CMOs). On the other side, the pharma industry has also been working intensively on lean programs to make their manufacturing more efficient and to reduce costs. It's clear that the industry hasn't been completely sedentary on this, but they are late moving down the path that other industries have already taken 10–15 years ago, such as automotive, consumer products and electronics.

Many large pharma companies see moving into the rapidly growing emerging markets as something that can offset losses incurred due to the patent cliff. How realistic is this?

U. Korneck: A lot of companies are striving to get into these rapidly growing markets. I believe there is up to $180 billion in pharmerging country markets. As to whether or not it's realistic: These are areas with huge populations, which means a huge patient base. The caveat is that people in these countries have much less money to spend on protecting and improving their health than their counterparts in the western world. The price for entering these markets is selling at a lower price and maintaining margins to serve at a lower cost. To put it into perspective: In the traditional markets – Japan, U.S., EU – more than $4,000 spent per capita per year. In these new markets, there's a per capita spending of anywhere between $40–400.

M. Jarosch: There is really a race going on to secure large volumes in those markets; companies can only offset those lower prices with economies of scale.

So what we are really talking about here is the sheer quantity of the patient base in these economies that is hoped to offset the losses that will come from these blockbusters going off patent?

M. Jarosch: Absolutely. The growth rates in the BRIC regions are very high. In China we're looking at 23–26 %; in Russia 12–15 %; and in India, 11–14 %.

If it wants to survive, big pharma has to change its business model.

The study recommends that established companies should by-pass their traditional business models and opt for new ones for the emerging markets. How are these new markets different from the traditional ones other than spending per capita?

M. Jarosch: Other than the lower amount spent, there is also a different infrastructure in those emerging markets with respect to logistics and sales capabilities and capacities. The population might be spread very differently either in population centers or very rural populations. While there are many differences in these markets, the key element is the lower spending per patient. This, of course, requires companies to also move their production to these lower-wage countries.

Many companies consider building greenfield projects in these pharmerging countries to be too risky and prefer to opt for partnerships instead. What do companies need to take into consideration when they are looking for a CRO or a CMO in these areas?

U. Korneck: Our study has shown that there are certain prerequisites. For example, quality really is a basic criterion that needs to be provided by the CRO or CMO. Delivery reliability is very important, as is then financial capability and stability, and flexibility.

M. Jarosch: Yes. Another important aspect is that CMOs are expected to have experience in cooperative sourcing. But there are also threats or risks that need to be managed at the pharma company: the transfer of know-how; the increasing administration and coordination costs; a risk of high staff turnover during the changes and change process; and establishing and monitoring quality standards at the CMO.

If we would look at all the Western-based CMOs and CROs, what does this growth in the emerging markets mean for them?

M. Jarosch: It means two things: In entails risks, but also new opportunities for them. As far as risk is concerned, Western CMOs are currently rather specialized, and they might get trapped in this niche. There is also strong pressure coming from originators on prices and costs – this could threaten the Western CMOs' business models.

On the other side, there are also new opportunities, too. CMOs could orchestrate the activities for the originators in emerging markets based on their experience as a CMO, and kind of work as an agent who takes part of the risk for the pharma company, but also receives then a price premium for this service. This would really transform the Western CMOs to more full-service providers. What this means is that the CMOs would need to follow the originators into these emerging markets with their Western know-how. An example for that is Lonza, who has taken that step and already built-up capacity in China, but still is a Western partner for the pharma companies.

This brings us back to the reluctance of most companies to put concrete in the ground in these pharmerging markets. Is this just a phenomenon for pharma companies, not for CMOs such as Lonza?

M. Jarosch: This is very strongly dependent on the experience of the respective pharma company. It also depends on the country's initiatives for encouraging investment. In Russia, the recently announced government support has made it an attractive region for pharma companies to invest directly. For example, AstraZeneca is currently investing over $150 million in the construction of a manufacturing plant there. In other countries the political risks might be very different, but Russia took that risk out. India, for example, is very stable, but also rather protectionist, because they have such a strong domestic pharma footprint.

What kind of a role will private equity companies play in the future of full-service providers?

U. Korneck: Private equity is usually very tight-lipped about their investment plans, and so the picture is not as clear as it is in other branches. However, we do see there a lot of small loose players all over the world, especially in Central and Eastern Europe. These small players are very specialized with big pharma companies who require full service as customers. There seems to be a textbook baseline for a buy-and-build strategy that some private equity companies pursue. When I look at the current landscape – at the Cardinal Health investment of Blackstone, for example – there is currently a buy-and-build strategy within the portfolio of some private equity companies.

M. Jarosch: We see an opportunity for private equity to consolidate the CMO markets, and create those full-service providers with big enough scale. Internally, the CMO market is quite fragmented, and the size and scale of the CMOs is limited. And there is certainly a trend in the pharma companies to reduce the number of their suppliers, because the complexity is growing so strongly. There is a real opportunity for consolidation here.

What risks are involved in outsourcing multiple facets of a business? Are there any parts that should definitely be kept internally?

U. Korneck: According to the study, there is no technology or no step of the value chain that should remain untouched. In the future, outsourcing along the value chain will focus on formulation and packaging. Also, solid forms – hard-capsule tablets, for example – are most suitable to outsourcing, but also 80 % of those surveyed said that also liquid and all other pharmaceutical technologies could be outsourced. The one exception is injections; only 50 % of participants said it was appropriate for outsourcing. In my opinion, the pharmaceutical industry is working on breaking some long-standing taboos in order to catch up with other industries. Designing new supply networks has the potential to break taboos from the top downwards.

What will the big pharma company of the future look like?

U. Korneck: If we look at the evolution of other industries that have gone through this process, it shouldn't be any different for pharma. Looking at food and consumer goods, the local supply for local demand strategy has been very successful. As for companies who don't own a strong pipeline and need to "harvest" products from the current portfolio, this local-to-local strategy could be a very good one for several reasons. For example, there is the advantage of taxation and overcoming local protectionism, but also being able to hedge currency and political risks by producing local with local costs and local sales.

Companies with strong pipelines are more interested in protecting their IP and keeping relevant processes in-house. For them, it would be more interesting to serve globally from one side and to finish locally.

If we look at the idea of a virtual supply chain – meaning outsourcing big portions of manufacturing and R&D – it should be noted that pharmaceutical companies that are pursuing this business model for the last years are entering the global pharmaceutical top 50 by sales. These companies' core competence is managing the brands and supply chains very differently than we see in traditional pharma comps. These companies are more flexible to act on the currently fast changing landscape. Traditional pharma recognized this as well. One thing all of our survey participants unanimously agreed on was that the current supply chain is completely different to the supply chain we'll see within the next five years.

chemanager-online.com/en/tags/outsourcing

Game Change

Continued Page 12

products or innovations with service providers. The dual-pressure fronts arising from the collapse in profitability in established markets and strong growth in pharmerging markets make this an untenable position, even in the medium term.

CMOs are being offered an opportunity – and they must rise to the challenge. Pharmaceutical companies have set out in no uncertain terms their expectations about working with third parties. They have made clear the conditions that must be fulfilled before engaging third-party suppliers in intermediate release, finished goods release, electronic information exchange and collaborative planning. Service providers would be wise to act quickly: Those that partner successfully with pharmaceutical companies can expect substantial business opportunities, involving the supply of large volumes and the chance to become an integral part of the supply chain.

But first they must become capable of providing a full-service offering – whether in logistics, warehousing or quality functions. By standardizing their IT systems to enable automatic information transfer they will win the favor of global pharmaceutical firms. Top ranked third-party providers must not shy away from asking for investment support. And most critically, they must show that they themselves are lean organizations with a business firmly focused on excellent delivery, cost effectiveness and continuous improvement.

Dr. Josef Packowski (CEO), Michael Jarosch, Ulrich Korneck, Camelot Management Consultants
Prof. Dr. Harald Augustin, ESB Business School

Contact:
Sebastian Deck
Camelot Management Consultants AG
Mannheim, Germany
Tel.: +49 621 86298 168
sde@camelot-mc.com
www.camelot-mc.com

The study will be published in November. You can order a copy of the study free of charge then at: http://www.camelot-mc.com/en/about-us/insights/surveys/

chemanager-online.com/en/tags/outsourcing

A Fragmented Industry

◀ Continued **Page 8**

P. Pollak: The future growth of the fine chemicals market depends mainly on the growth of the pharmaceutical industry and the trend in outsourcing. The development of the Western fine chemicals market alone depends on the globalization. Using optimistic/pessimistic assumptions for the three variables the following API growth scenarios result.

Due to the impact of reduced growth of the pharma industry on the one hand, and increased outsourcing on the other hand, the value of captive API production within the pharma industry will remain flat at about $33 billion/year throughout the 2010–2020 period.

In scenario I, the API production in the European and U.S. fine chemical industries will continue to grow, albeit at a slower rate than Asia's (+6% p.a. against +10% p.a.). demand and globalization. In scenario II, both the EU and U.S. will be negatively affected by the twofold impact of soft demand and globalization. The production value will be about halved. In contrast, the production value of the Asian fine chemical industry will more than double.

What are major market trends in terms of customer requirements?

P. Pollak: In the medicine chests of the people living in emerging countries, more and more Western type pharmaceuticals will be stored. Worldwide, originator drugs will be substituted by generic versions. Therefore, custom manufacturing of pharmaceutical fine chemicals will lose ground against API-for-generics production.

On the M&A market, there have been two important developments since the beginning of the new millennium. In order to get a stronger grip on the Western markets, cash-rich Indian pharmaceutical and fine chemical companies entered into an acquisition spree of Western fine chemical/generics companies. Between 2004 and 2006 alone, more than 20 deals were completed. Like their European counterparts, which had a negative experience with their transatlantic expansions in the 1990s, not all Indian overseas acquisitions were a sweeping success. More recently, financial investors have begun acquiring mainly European fine chemical companies. International Chemical Investor Group (ICIG) has been particularly active. Since inception in 2004, ICIG, dubbed one of the most prolific buyers of fine chemical assets in recent years has acquired 16 independent chemicals and pharmaceutical businesses with total sales of approximately €700 million. The figure does not include ICIG's most recent acquisition, namely Roche's (formerly Syntex's) large fine chemical plant in Boulder, Colo. ICIG's portfolio of pharma and fine chemical companies is managed as CordenPharma.

How can traditional fine chemical companies succeed in this challenging competitive environment?

P. Pollak: Organic chemical synthesis is a mature science. It did not evolve much beyond the substitution of wood by stainless or glass-lined steel as construction material for chemical reactors, where chemical reactions developed during the golden years of the dyestuff industry are performed. Except a few niche technologies, the capability to operate a GMP multipurpose plant is hardly a differentiator any more – with one notable exception: biotechnology. Especially mammalian cell technology has a big future. It is required for producing the modern big molecule APIs, dominating for instance the market for oncology drugs.

However, entry barriers are high. Existing facilities cannot be used and demand for containment has reached a new dimension. On the other hand, both exclusive synthesis of biopharmaceutical APIs for the innovator companies and production of APIs for the fledgling generic versions of biopharmaceuticals, the biosimilars represent an attractive opportunity for entrepreneurial companies with a full war chest. In the more distant future, stem cell technology could become a major tool in medicine. It allows substitution of damaged human cells with new, healthier versions that could eventually lead to cure for many chronic diseases, from macular degeneration to Alzheimer, diabetes, heart disease and spinal cord injury.

In terms of size, mid-sized, family owned companies have several advantages. They are not afflicted by the imperative to show better financial results from quarter to quarter – in a volatile market! The CEO gets involved in projects, visits customers and takes binding decisions. As the size of a production campaign for any given fine chemical rarely exceeds a few ten tons, there also is no economy of size in manufacturing. Fine chemicals have to be produced in campaigns in multipurpose plants regardless the size of the company. In a business, where "low cost" is more important than "over-the-fence" supply, the Asian fine chemical companies have a big advantage.

What is the single most important success factor for a fine chemical company?

P. Pollak: A track record of successfully completed new product projects with several big pharma companies.

chemanager-online.com/en/tags/fine-chemicals

Saudi Aramco, Dow Sign Sadara JV

Dow Chemical and Saudi Aramco have signed a joint venture shareholders agreement for Sadara Chemical Company. The joint venture is expected to drive downstream industries and support economic growth in Kingdom and emerging markets, with production to start in the second half of 2015. The financial aspects of the deal were not revealed.

Saudi Aramco President and Chief Executive Officer Khalid A. Al-Falih and Dow Chairman and Chief Executive Officer Andrew Liveris were the signatories. Once complete, the JV complex will be one of the world's largest integrated chemical facilities, and the largest ever built in one single phase. In July, the respective boards authorized for a go ahead with the joint venture.

The manufacturing units will produce a wide range of performance products such as polyurethanes, propylene oxide, propylene glycol, elastomers, linear low density polyethylene, low density polyethylene, glycol ethers and amines. Sadara will market products within a regional zone of eight countries, including the Kingdom. Dow said it expects Sadara to deliver annual revenues of approximately $10 billion within a few years of operation. ■

DuPont: $500 Million Kevlar Facility

DuPont has started up its $500 million Cooper River Kevlar facility near Charleston, South Carolina.

The Cooper River Kevlar plant uses state-of-the-art technology that the company said will allow it to meet increased customer demand for advanced protective materials in emerging industries around the world. Commercial supply will begin by the end of the year.

Overall global production capacity for Kevlar will increase initially by 25% and is expected to grow by 40%, with planned productivity improvements and continued technology developments over the next two years, DuPont said. ■

Clariant Sells Polysilazane Coatings

Clariant said it is selling its polysilazane coatings business including the production site in India to AZ Electronic Materials (AZ) for approximately €4 million.

Under the terms of the agreement, Clariant retains the exclusive right to develop and use polysilazanes for composite materials and ceramics. Clariant will continue its development in the area of ceramic precursors and fibers based on polysilazanes. It is for this reason that Clariant also concluded a long-term supply agreement for polysilazanes with AZ.

The company said it is divesting the business in order to increase operational efficiency and in order to refocus management time on core new business development activities. ■

Dow Sells Polypropylene Business

Dow Chemical said that it has closed the sale of its global Polypropylene business to Braskem.

In addition to the deal, the two companies will continue to evaluate potential future collaborations on growth opportunities in connection to their strategies.

The assets involved in the deal included Dow's polypropylene manufacturing facilities at Schkopau and Wesseling, Germany, and Freeport and Seadrift, Texas.

Dow's Polypropylene Licensing & Catalyst business and related catalyst facilities were excluded from the scope of the deal. ■

Air Products Buys 25% Stake

Air Products & Chemicals announced it has agreed to acquire a 25% stake in the gases and equipment businesses of Abdullah Hashim Industrial Gases & Equipment. The transaction is subject to regulatory approval and customary local closing conditions. Financial terms are not being disclosed. AHG is a company of the privately-owned Abdullah Hashim Group, based in The Kingdom of Saudi Arabia.

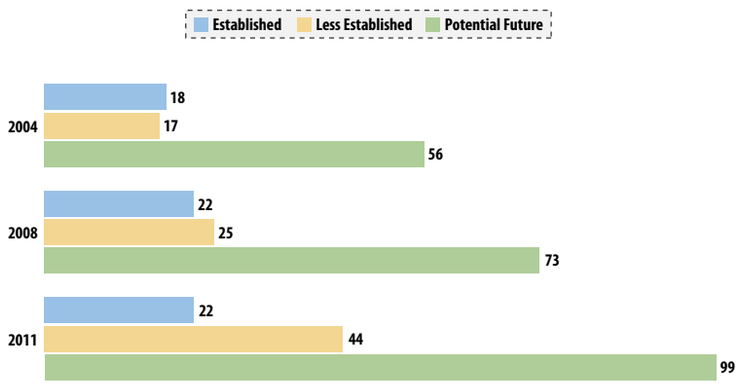
AHG has three main production locations in Dammam, Jeddah and Riyadh, plus distribution centers at key locations across The Kingdom. AHG also has a purchase agreement with National Industrial Gases Companyat Jubail and Yanbu for liquid products. ■

API Sourcing in China and India

Is Asia the Only Option for the Future?

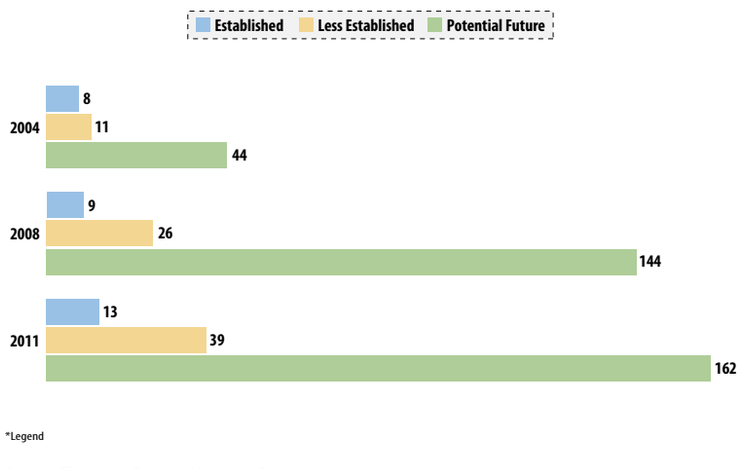
Paradigm Shift – The number of API manufacturers in India and China focused on supplying active ingredients to regulated markets has grown considerably over the past few years, which can be attributed to the increasing focus by dose companies based in regulated markets to find ways of lowering costs, including those for active ingredients.

API Manufacturers in India Fig. 1



Source: Thomson Reuters Newport Premium © CHEManager Europe

API Manufacturers in China Fig. 2



*Legend

Source: Thomson Reuters Newport Premium © CHEManager Europe

Many of these new API manufacturers have also invested in finished dose development and manufacturing, frequently utilizing their own active ingredients. However, these regions that once offered significantly lower costs are experiencing a rise in energy and labor costs, in addition to re-emerging competition from established European API manufacturers and speculation about the emergence of a second-wave of even-lower cost sourcing destinations.

Thomson Reuters assesses the capabilities and experience of API manufacturers according to a proprietary scheme based on objective regulatory data. Companies range from those focused on supplying their local market to companies with years of experience supplying highly regulated markets. Although a large number of the companies in India and China continue to be locally focused, many have invested in facility upgrades and supplying regulated markets (fig. 1–2).

When sourcing from India, the cost advantages range from basic research and development to finished dose formulation. There are vast reserves of local labor and chemistry talent, and intellectual property protection is improving. The number of FDA approved API and finished dose facilities in India is large and continues to grow. Many Indian companies have moved from supplying API into the U.S. and the EU to supplying finished doses. There has been an almost exponential increase in the number of Indian companies' Abbreviated New Drug Application (ANDA) approvals over the past 10 years.

When sourcing from China, there is massive scale and capacity available, and the Chinese government continues to invest strongly in the local manufacturing industry. China has seemingly unlimited supplies of capable, talented scientists and engineers, as well as better infrastructure than India. The number of U.S. FDA inspected facilities in China has increased over the past few years and companies are continuing to invest in quality upgrades. China also has easier access to a wide variety of intermediates and chemicals. Where China has surpassed India is in its classes of fermentation-based APIs, intermediates and many base chemicals. At the end of 2010, the first Chinese ANDA was approved and additional filings by Chinese companies are awaiting approval. At present, four Chinese groups hold a combined 13 ANDAs with final U.S. FDA approval.

The geographical shift in API sourcing over the past decade is quite apparent when we look at U.S. Drug Master File (DMF) filings by region. Although filing a DMF doesn't necessarily mean that a company is supplying the product into the U.S., the notable rise in the number of U.S. DMFs held by Indian companies and the gains that Chinese companies have made is quite significant. The number of U.S. FDA inspections of facilities in these regions has also risen dramatically. In 2004, less than 10 companies in India and China were inspected, while in 2009 the number had risen to over 50 companies being inspected. Almost half of the COSs filed in the past few years have been filed by companies from India and China.

However, there are challenges as well. Salaries in China and India are increasing much faster when compared to regulated markets. The high turnover of personnel in China and India also adds to labor costs. Environmental compliance is a major expense in China, and factories that cannot invest in sufficient upgrades are closing. Furthermore, when sourcing from India and China, there is a lack of senior level talent in certain areas such as quality assurance and project management. There is also a pervasive focus on short-term rather than long-term returns.

European Comeback

In addition to the rising manufacturing costs in India and China, recent sourcing issues involving import bans have placed European API manufacturers in a better position to compete. Almost all of the suspended COSs are linked to companies from these two countries as well because they failed or refused inspections. The increasing finished dose manufacturing in India has also offered opportunities for European manufacturers to supply API to Indian companies formulating products bound for the U.S. and EU markets.

European API manufacturers with strong technological capabilities in niche areas will also be in a position to take advantage of the many small volume APIs coming off patent after 2015. Companies in regulated markets have also made themselves more competitive by entering into joint ventures with emerging market players or building manufacturing facilities in emerging markets, allowing them to circumvent patents and supplementary protection certificates.

Emerging Markets

Rising costs in India and China have also prompted companies to consider other countries as sourcing alternatives. However, when compared to the over 1,500 API manufacturers in India and China, there is little API manufacturing in other emerging markets, such as Latin America and Russia. Part of the Russian government's planned $1.3 billion investment into the Russian pharmaceutical market is intended to improve and increase local API production. Also, the low number of facilities that have implemented GMP will be a considerable obstacle to supplying API into regulated markets. Today, most of the manufacturers in the second wave of emerging markets offer little experience in regulated markets, and there is no indication of better price at acceptable quality than in India or China. Companies looking at alternative sourcing options may have better luck in Eastern Europe, South Korea or Taiwan.

Industry competition will continue to push both API and dose manufacturers to search for lower costs and strategic advantages. However, we believe that there will also be increased focus on quality and reliability, ultimately leading to a more level playing field between India, China and Europe.

▶ Contacts:
Bob Kennedy, Manager of Industry Research, Thomson Reuters
robert.kennedy@thomsonreuters.com

Molly Bowman, Manager, Small Molecule Research, Thomson Reuters
molly.bowman@thomsonreuters.com

www.thomsonreuters.com

chemanager-online.com/en/tags/api-sourcing

A Changing World for CMOs

Consolidation in Pharma a Win for Custom Manufacturing

Advantages – With more and more players in big pharma looking to outsource in order to focus on core competencies, custom manufacturers stand to benefit from this shift.

Mark Griffiths
CEO, Carbogen Amcis

Wolfgang Schmitz
CEO, Saltigo

Nick Johnson
Strategic Marketing Manager, SAFC

Jean Bléhaut
Director, Marketing & Business Development, Novasep

The most exciting trend in pharma custom manufacturing is …

M. Griffiths (Carbogen Amcis): … changes in big pharma. Costs of bringing a new drug to the market rose above $1 billion according the PhRMA due to longer clinical trials and tougher regulations for drug approvals. The numbers of NCEs approved by the FDA declined and the patent cliff has increased competition from generics drugs. Job cuts, mega merges and co-development programs are some of the strategies implemented to reduce costs, improve profit margins and mitigate the risk of drug development. Big pharma is gradually transitioning away from the historical heartland of primary care therapeutics and the blockbuster model towards hard to treat conditions with requiring high value drugs targeting complex niche diseases such as oncology. Access to leading edge technology and specialized skills is paramount for the development and manufacture of high value small molecules, biologics and conjugates. Consequently, the trend among many CMOs is to invest in highly specialized technologies necessary to handle complex drugs.

W. Schmitz (Saltigo): … the full integration of the custom manufacturer in the business process of the customer. Whereas in the past only the product has been bought by the customer nowadays the custom manufacturer has to provide a wide variety of services. These product related services, like quality risk assessments, definition of design of experiments and design spaces, etc., and the integration of chemistry and technology at the custom manufacturer site allow the customer to focus on its core competencies and hence reduces the time to market. The integration of the CMO in the business process leads to an alignment of the two parties and ideally to a long lasting partnership.

N. Johnson (SAFC): … pharma companies outsourcing, continuing the shift away from manufacturing in their own assets and opening up major opportunities for the contract manufacturing sector. While a large proportion of pharmaceutical manufacture remains within pharma companies' assets, eventually, an even greater proportion will reach the merchant market.

Pharma companies are also continuing to develop innovative, highly novel therapeutics, which again creates new demands and requirements for CMOs. To capitalize on these new opportunities, CMOs need to take a technology leadership position and also to invest in the necessary capabilities and infrastructure.

J. Bléhaut (Novasep): … the increasing complexity of the new APIs reaching the market. Over the years, the new synthetic molecules developed in the pharmaceutical industry have become larger and more challenging to synthesize. This trend is driven by two major factors: the development of more and more targeted therapies, leading to specifically designed, highly functionalized molecules; and the intellectual property mine field, forcing innovators to look for unpatented molecular structures to protect their future markets. This has impacted on our customer's expectations, they need chiral separation, purification of molecules that are insoluble in organic solvents, thermally labile, contain sensitive functionalities, cannot crystallize, etc.

The biggest challenge we face in custom manufacturing today is …

M. Griffiths (Carbogen Amcis): … the fact that world we inhabit as CMOs has changed markedly in the last four years. Continuing retrenchment and consolidation of our large pharma customers' activities and cash available for small biotechs to pursue innovative NCEs will be key in the next five years. With large pharma divesting much of their historical API manufacturing operations and with the biotech sector continuing to struggle for funding, a new model is starting to become reality.

Custom Manufacturing

Big pharma are increasingly filling their pipelines through in-licensing innovative therapeutics from biotechs, which in turn provides additional funding for the biotech sector to re-invest. For CMOs this means that strong relationships across both biotech and pharma sectors is increasingly a requirement. CMO organizations like the Dishman group having significant exposure in both areas clearly have an advantage here. Business mix is likewise key for CMOs, those who are over exposed to and over reliant on early development revenues are disadvantaged as the pharma industry realigns itself to a greater emphasis on specialist drug platforms, biologics and generic products.

W. Schmitz (Saltigo): … the huge overcapacity and the overdue market consolidation in combination with the trend towards shorter timelines, less new molecular entities, continuous price pressure due to health care reforms and blockbusters going off patent.

Continues **Page 17** ▶

Fine Chemicals Developing Well In 2011

Agro Segment Showing Particularly Strong Growth

Showing Muscle – Fine chemicals have had a strong showing in 2011, thanks in particular to a strong agro segment. Also, the industry is seeing more requests for challenging chemical syntheses from blue-chip life science and chemical companies.

Dr. Martin Wienkenhöver
CEO, CABB

Dr. Peter Seufer-Wasserthal
SVP Pharmaceuticals, Codexis

Dr. Jörn Winterfeld
Director Business Line Pharma/Agro at Wacker Biosolutions, Wacker

We see Asia as …

Dr. M. Wienkenhöver (CABB): … an attractive market for our products, especially in the acetyls business. CABB is meeting the opportunity head on, having established a foothold in Asia in 2008 by taking over Karnavati Rasayan, India's market leader operating the country's biggest MCA (monochloroacetic acid) plant. This was only the first step. We are looking for further regionalization of our business into Asia, especially China, the biggest market for MCA globally. Asia as a whole – and particularly China – is increasing the quality requirements for this important chemical building block, particularly as it intends to participate in the export area for the downstream products.

Dr. P. Seufer-Wasserthal (Codexis): … as a great and proven partner for using our enzymes to produce pharma intermediates and APIs, and a growing market for our intermediates and APIs. We have been selling our products in India for many years to a growing number of customers. In January, we were very pleased to announce a collaboration with Dainippon Sumitomo Pharma, one of Japan's 10 largest pharmaceutical manufacturers.

Dr. J. Winterfeld (Wacker): … an important focus region for the Wacker Group. The company has already invested heavily in production plants – for instance for silicones – and set up a comprehensive sales organization in countries like China, Japan, Korea and India. Concerning the fine chemicals segment, we will continue to focus on our core markets in Europe and the U.S. Asian countries like China and India also offer large business opportunities and growth prospects for fine chemicals. But on the other hand, it is a very competitive region with benefits for domestic producers.

The business of fine chemicals in 2011 is …

Dr. M. Wienkenhöver (CABB): … developing well, driven by extraordinary growth in the agro chemicals. But also custom manufacturing for pharma intermediates and for the personal care segment was strong.

Dr. P. Seufer-Wasserthal (Codexis): … is growing because of the re-structuring at our customers. We find our pharmaceutical customers turning to qualified suppliers such as Codexis for process development of intermediate and API manufacturing.

Dr. J. Winterfeld (Wacker): … improving further, following the economic crisis in 2009. Sales and profitability recovered in 2010 and in the first half of 2011 and were driven by a strong market demand, especially from industrial applications like automotive and construction. Wacker, too, benefits from this positive business environment by selling organic fine chemicals like acetyl acetone, chlorinated carbonyl compounds and special silanes.

The most promising trend in fine chemicals is …

Dr. M. Wienkenhöver (CABB): … an increasing demand for custom manufacturing services coming from the blue chip life science and chemical majors. Our clients have now asked us for more innovative and complex products that until recently they were manufacturing in-house. Overall, we see a strong growth in the outsourcing of fine chemicals – especially of more challenging chemical syntheses. CABB can apply its core competencies to the customers' – and our own – benefit. We are prepared to grow with the customers by investing in these partially complex synthesis routes and by continuing to provide on-time, best-in-class service and reliability.

Dr. P. Seufer-Wasserthal (Codexis): … openness for the use of new technologies in the manufacture of the products rather than only moving to lower cost areas to improve economics.

Dr. J. Winterfeld (Wacker): … beside a growing market place, especially for agro chemicals and some industrial applications, the improvement of ecological compliance of the chemical industry – also in the emerging countries.

The future of fine chemicals is …

Dr. M. Wienkenhöver (CABB): … looking attractive for those companies who can add real value to the business of their customers. CABB thrives to be the partner of choice by applying intelligent solutions and innovative technical and chemical concepts, supported by sizable investments both into assets and know-how; as well as a well-perceived service offering enabling the customers to concentrate on their core business considerations and rely on a strong outsourcing partner.

Dr. P. Seufer-Wasserthal (Codexis): … in more advanced and more complicated products using new technologies. We find customers are rapidly adopting biocatalysis into their operations as this technology has moved broadly into the mainstream.

Dr. J. Winterfeld (Wacker): … positive, with a growing global market demand. However, business will remain competitive, with competition coming especially from Asia. Wacker considers its backward-integration to basic chemicals, the long-standing know-how and experience regarding certain technologies like chlorinations, silane and ketene chemistry, as well as production at a fully integrated site as particular strengths for the fine chemicals business. Constant process improvements and upgrade in technology are also key success factors in the fine chemicals field.

Fine Chemicals

Consolidation in the fine chemicals industry will …

Dr. M. Wienkenhöver (CABB): … further continue. CABB just acquired KemFine in August with the support of our new owner, Bridgepoint. For CABB KemFine is absolutely the right partner to help grow and develop our business further – especially in the area of custom manufacturing.

Dr. P. Seufer-Wasserthal (Codexis): … happen! It also means that synergies will be used in existing Western plants and that these companies will have to deal with technologies they have not been familiar with. This allows for new technologies to be used as well.

Dr. J. Winterfeld (Wacker): … continue, since it is a very fragmented industry. Many small players may vanish or merge to attain the so-called critical mass. This trend includes producers in China.

chemanager-online.com/en/tags/fine-chemicals

Custom Manufacturing

◀ Continued **Page 16**

N. Johnson (SAFC): … the fact that market for general small molecule contract manufacturing remains highly competitive, with a significant supply/demand imbalance. Coupled with this is the general reduction in R&D funding, with 2009 being the first year that the total spend actually decreased. Collectively these points mean challenged profitability in certain segments and at some point there will need to be some significant asset closures to allow these over-capacity segments to return to profitability.

J. Bléhaut (Novasep): … the perception of our value by the customer. Lately, fine chemical outsourcing decisions have often been essentially driven by price considerations. However, fundamental factors have sometimes been overlooked by pharmaceutical companies. For instance the lack of professional project management on the supplier's side may have dramatic impact on the timing of delivery of an intermediate for clinical trials, thereby delaying critical development milestones. This is particularly relevant as more and more lead compounds are developed by emerging pharmaceutical companies, dealing with limited resources and very tight timelines to carry on with the development process. For these companies, the delay of a clinical milestone can threaten their existence. They really need partners they can trust.

For custom manufacturing, Asia is …

M. Griffiths (Carbogen Amcis): … a factor. In 2010, Western companies were still the preferred outsourcing partners for premium services and products e.g. complex new chemical entities, technical flexibility, speed and commercialization expertise. The Dishman group has a significant presence in Asia which allows the group as a whole, including Carbogen Amcis traditional costumer base the advantage of leveraging the right skills and assets at the right time throughout the drug development process and during product lifecycle management.

W. Schmitz (Saltigo): …a challenge and, at the same time, a chance.

Saltigo benefits indirectly through its customers from the trend to expand business in Asian regions. The Asian competition has been rapidly growing in recent years and our customers from different industries have been exploring this supply base using multiple strategies.

Saltigo benefits in Asia directly from the network that its mother company Lanxess has built in Asia by building various production sites. Saltigo can offer unique services especially with regard to procurement by utilizing this network and the direct access it provides.

N. Johnson (SAFC): … an established base for generic APIs and early-stage intermediates. However, in custom manufacturing, customers need open communication, reliability, excellence in quality and compliance and manufacturing efficiencies. Taken collectively, these are characteristics not found to be localized regionally, but are rather characteristics of individual companies and their capabilities and culture.

J. Bléhaut (Novasep): … an opportunity, but also a market where savings might come at a cost.

For us, the Eastern market place represents an opportunity to source early intermediates in a cost effective manner, and we ensure that we make the best of it. However, we remain extremely cautious in the establishment and control of our supply chain to avoid any delays which would impact the time to market for our customers.

Now, from a competition point of view, Asian companies undoubtedly present financial advantages but many other elements are to be accounted for. The custom manufacturing market is a complex equation in which the human factor has become the precious resource nowadays. Geographical and cultural proximities are advantages Western Europe companies will always retain for their European and U.S. customers. Simple aspects like shorter travel times and less jet lag for example – which both impact on productivity – can make the difference. Combined with strong relationships and mutual trust we develop with our clients, this makes European CMO companies attractive for the western industries.

In 10 years, custom manufacturing will be …

M. Griffiths (Carbogen Amcis): In the future, CMOs will increasingly be required to offer a more integrated approach for development and manufacture of drug products, where complimentary services will be offered under one umbrella (such as MedChem, early phase development, formulation services, commercialization and integrated commercial supply of drug substance and drug product). The ultimate goal is to reduce time to market through streamlined project management, or at least to "fail fast." We expect to see a more intimately integrated approach among drug substance and drug product manufacture at least in the development stages of NCEs.

W. Schmitz (Saltigo): … influenced by growing population, resource scarcity, increasing urbanization and mobility. In the long run, we see a positive market environment for agrochemicals and pharmaceuticals. This comes from the increasing demand and interest in biofuels and changing eating habits, particularly in Asia. And we see also growth potential in the pharmaceutical sector, because big pharma companies are outsourcing more and more to concentrate on their core strengths and emerging pharma companies continue to drive new drug developments through innovation.

N. Johnson (SAFC): As pharma companies continue to simplify their supply base, we are likely to see further consolidation amongst custom manufacturers and fine chemical companies, with the possible exit of some lower performing players. We expect that strategic relationships will transition to symbiotic inter-dependency, with more integrated and productive working practices. Additionally the trend towards more niche therapies and personalization of medicines will require custom manufacturers to reconsider their asset base and manufacturing technologies according to the product needs of these developing areas.

J. Bléhaut (Novasep): … certainly more concentrated. At the moment this market is constituted by a multitude of relatively small companies. In the coming years a more limited number of larger companies will emerge from these. In addition, specialist CMOs like us, able to solve certain types of manufacturing challenges (coupling multi-step synthesis with advanced purification technologies to make complex APIs or global manufacturing of antibody-drug conjugates are good examples) are aiming at becoming real references on the market place.

Our most crucial differentiating competence is …

M. Griffiths (Carbogen Amcis): … the quality of our people throughout the entire group, who offer both broad and deep expertise in many areas, from chiral organic chemistry, peptide chemistry to complex separation sciences and their absolute passion for problem solving and customer service. The majority of the projects we handle are highly technically demanding and require an open approach and effective communication to quickly define the project's specifications and deliverables, the must-have versus nice-to-have, and the project's timeline.

W. Schmitz (Saltigo): …our expertise in the chemical development in combination with technology, upscaling and refinement of chemical processes for efficient, cost-effective and safe production of complex molecules, state of the art waste disposal and HSE compliance. Using this core competence to meet customer demands is the cornerstone to generate profitability.

Our strategy as a service-provider combines professional outsourcing, first-rate method development and ongoing improvement with the aim of achieving a high degree of flexibility and reliability, while keeping the overall cost of the products that we supply to customers, as low as possible.

N. Johnson (SAFC): … not easy to define as a single characteristic. For sustainable performance a custom manufacturer needs to build close relationships with their customer, with flexibility and commitment to quality and service. It is also paramount to develop deep and broad technology and capabilities to address the wider needs of the customer. In isolation, none of these elements is sufficient to be successful.

J. Bléhaut (Novasep): … our ability to offer choice to our customers. We have a unique position on the market place as a technology expert and a process developer. We can supply our client with purification equipment that we develop within our company and/or provide them with the custom synthesis and purification of their products. This places us as the ideal partner for development through large scale manufacturing.

In addition, our presence in many markets (including pharmaceutical, biopharmaceutical, food and functional ingredients, bio industries, agrochemicals …) enables cross-fertilization of our know-how, resulting in the design of smarter and more cost effective processes.

chemanager-online.com/en/tags/custom-manufacturing

Functional Ingredients

Excipients Not Just Additives Anymore

Excipients

Multifunctional – The expectations on excipients have grown over the last years. No longer seen as mere fillers and binders, pharma is now looking toward excipients that add value to their end product and are multifunctional.

The most exciting trend in excipients is …

Hans Ole Klingenberg (global marketing director at Novozymes): … the pharmaceutical industry's shift towards recognizing excipients as functional ingredients rather than non-functional additives. As a result, manufacturers are increasingly looking for novel, value-added multifunctional excipients, that offer real advantages to both the manufacturer and patients. In addition, advances in technology offer new opportunities to explore simpler product formulations with reduced numbers of excipients.

For the excipient business, Asia is …

H. O. Klingenberg (Novozymes): … one of the fastest growing countries in terms of innovation. For example, in China, recent years have seen double-digit growth in the country's biotechnology industry, transforming it into one of the fastest growing in terms of biotech innovation. Novozymes was one of the first western biotech companies to enter China and has more than 20 years' experience running and operating facilities in the country. With this experience in hand, Novozymes is now looking to push the boundaries further with the opening of a new dedicated Q7 cGMP facility for the production of state of the art cGMP grade hyaluronic acid (HA) making it suitable for biomedical and pharmaceutical applications.

cGMP certification for excipients manufacturers is …

H. O. Klingenberg (Novozymes): … vital to ensure that drug development processes are as efficient and effective as possible. Working with raw materials that are already Q7 compliant can help medical device and pharmaceutical manufacturers to reduce testing time, minimize documentation requirements, save on manufacturing costs and take products to market faster.

Our most crucial differentiating competence is …

H. O. Klingenberg (Novozymes): … Novozymes' commitment to providing solutions that help its customers solve their most demanding challenges. The company does this by providing access to high-quality ingredients, proprietary technologies and unique know-how, contributing toward the development of improved drug products that provide real and sustainable benefits to patients. As a company, we are constantly reviewing industry trends and looking for new opportunities to improve our customers' processes by developing better and safer alternatives to the products that they are currently marketing. However, we are more than a mere supplier of enabling technologies or products; we see our relationship with each customer as a partnership. By combining our scientists' unique knowledge of Novozymes' biological solutions with the customers' specific application knowledge, we work with our customers to find the right answer to their development challenges.

In excipients, innovation is driven by …

H. O. Klingenberg (Novozymes): … the demand for safe and consistent biologically-derived solutions that can ultimately improve treatments for patients. Novozymes develops and manufactures high-quality, animal-free, recombinant ingredients and technologies. We provide pharmaceutical manufacturers with proven options based on our established technology platform that has been developed over the last 50 years, and which will enable them to develop safer and more consistent products. Currently, 14% of Novozymes' total revenue is spent on R&D projects.

chemanager-online.com/en/tags/exipients

‘As Reliable as a Swiss Watch’

Innovation Expected from API Manufacturers

Up To Task – Facing a huge patent cliff and a less-than-robust pipeline, pharma companies must look to customized and personalized medicines. This is where API manufacturers are expected to step up to the plate.

Markus Blocher
CEO, Dottikon

Dr. Andreas Dietrich
Vice President Launch and Strategic Products at Boehringer Ingelheim

Heinz Sieger
CEO, CU Chemie Uetikon

For our API business, Asia is …

M. Blocher (Dottikon): … still a minor market today. Margins are rapidly decreasing with increasing number of players attracted by high growth rates of non-branded and branded generics in pharmerging markets such as Eastern Europe and Latin America besides Asia. In addition, intensified price pressure by regulation is taking place as governments seek to keep healthcare spending under control, similar to industrialized countries. China plans to motivate scientists from the U.S. with hundreds of billions to start up biotechs within China, and Indian generics manufacturers are increasing their efforts to develop their own branded drugs. Despite these facts, the custom manufacturing for Asian biotechs and drug innovators is still in the introduction and years from entering the growth phase. Therefore, for the time being, Asia remains a source for low-cost starting material and generic APIs, and a direct and indirect market to sell high-valued intermediates finally ending up in generics.

Dr. A. Dietrich (Vice President Launch and Strategic Products at Boehringer Ingelheim): … remains important. Macroeconomic indicators point to continued growth of the pharmaceutical market. Of course, each region of the world influences growth in different ways. Changes in demographics in Europe, rising disposable income in Asia, wider availability of health insurance schemes around the world are just a few changes to mention here. The Asia-Pacific pharmaceutical market has been emerging as a fast growing region over the past decade. The reason for these changes can in particular be attributed to a favorable manufacturing cost environment and the need to access better healthcare. Consequently, Asia has seen important developments in contract manufacturing, especially for APIs and generics, and has to no surprise positioned itself as a frontrunner of global API production. We believe this positive development will continue to strengthen Asia as a global API production hub, a trend which is predominantly driven by continued pressure around the world on drug product cost, as well as by technology and partnership advancements.

H. Sieger (CEO, CU Chemie Uetikon): … an interesting market, offering opportunities of economic growth. With the two largest populations residing in India and China the drug market in Asia and in the other E7 countries is expected still to grow much faster than in the developed markets and will reach a market share of about 20% in 2020 that means will at least double within the next nine years.

Especially because of our GMP compliance, our high and reliable quality in general and the trend setting GMP design of our production facility, we see good chances to grow our business in these countries.

The most promising trend in APIs is …

M. Blocher (Dottikon): … that the number of new drug approvals by the FDA in the first half of 2011 has already exceeded the total of 2010 approvals, despite high attrition rates and therefore low number of NDAs for approval. The majority of approvals involves significant improvements over existing treatment options and may mark the beginning of a new era of customized and personalized medicines. Indications and treatments of the newly approved drugs typically address small and highly targeted patient groups. The novel chemical core structures of these APIs often require state-of-the-art technology in the synthesis. However, their significantly lower annual volume needs economically disfavor commoditized monoplant manufacturing. The demand for rapid process development, reliable scale-up and safe manufacturing of commercial API quantities is increasing. This is a clear effect from the deferral of chemical process development to later clinical phases with the aim to avoid R&D spend on unsuccessful projects; and the need to substitute each lost blockbuster by a multiple of smaller new drugs. In essence, the future successful contract manufacturing consists of exclusive synthesis by partnering with an experienced, reliable, highly flexible supplier having the right versatile technology portfolio to tackle today’s chemical manufacturing control challenges.

Dr. A. Dietrich (Boehringer Ingelheim): … will be influenced by several factors. Finding new and innovative synthetic routes, and continued manufacturing efficiency gains to lower overall API cost will remain important. Emerging markets are benefiting from expansion of medical infrastructures and an increase in per-capita income. A successful growing penetration of health insurance, a growing aging population and information campaigns of pharmaceutical companies prepare the way for API market growth. Also biopharmaceutical APIs, which currently make up the smaller part of the global API market compared with chemically produced counterparts, are of interest. The growth prospects for these kinds of actives represent attractive opportunities for growth for innovator companies, as well as for biosimilar API manufacturers.

H. Sieger (CU Chemie Uetikon): … stricter regulatory legislation and better international coordination and cooperation. The New Falsified Medicines Directive, which we very hard worked for in the last 10 years with APIC and EFCG and which has been in place since July 1 will change the API supply chain and is a good step forward toward towards safe and trustworthy medication especially in Europe. The regulation will also help to level the playing field for fine chemical companies in Europe.

The most drastic change that has happened in the last 10 years is …

M. Blocher (Dottikon): … the loss of the U.S.’ hegemonial power, symbolically initiated by the collapse of the World Trade Center at the beginning of this century. Lacking of financial resources and political will, unilateral global stability will no longer be provided by the U.S. A reverse of globalization to regional fragmentation is the result and will affect global supply chains, also of pharmaceutical industries. The cascade of financial market and government debt crises drastically increased pressure to reduce healthcare spend in all industrialized countries. Generation promises inherent in the social security systems in combination with over-aging populations exacerbate this situation. This is changing the pharmaceutical industry structure fundamentally. For instance, pharma manufacturing capacity is dispatched, consolidated and reduced employing the aid of short-term cash flow maximizing financial investors as undertakers. In the long run, this improves the bargaining power of financially sound, experienced, technology-leading and reliable manufacturers.

Dr. A. Dietrich (Boehringer Ingelheim): … cost pressure on API synthesis in manufacturing pharma companies and their inability to maintain margins once products are off patent. In response to this problem, many companies turned to Asian manufacturers that were trying to gain market access by offering products at a lower-priced starting point. While corresponding quality and regulatory understanding was still in need of development, today’s Asian manufacturers have become better at responding to needs which go beyond price. In response to this development, many Western API manufacturing pharma companies have expanded their API outsourcing activities beyond the traditional high quality European or North American partners to also include upcoming Asian manufacturers. For the pharma companies, it is not only an opportunity to focus more on their core competencies developing innovative medicines, but it is also a way to offload their balance sheets with manufacturing assets. The manufacturing and growing supply of APIs out of Asia has enjoyed the trend of diversification and globalization of the supplier base. In the long-run, these advances will increase the cost for CMO services out of Asia and will shift towards meeting a growing local demand. Consequently, one could expect that during this decade the manufacturing cost advantage between East and West will shrink and eventually vanish. In parallel, the need of Western pharmaceutical manufacturers to select strategic suppliers within reach will continue to be important. Not only do they want to maintain a supplier base close to their wholesaler markets, but they also require expertise and understanding of the local regulatory environment and launch expertise. One can already see today operational excellence advances and cost focus, which have transformed some Western API manufacturers into global cost competitive players – without jeopardizing the expected high standards of launch services or product quality.

H. Sieger (CU Chemie Uetikon): … the global, worldwide interconnection and expansion of information exchange and technology. This has improved the availability of health care data, our knowledge management and the speed and scale of economy, creating thereby major opportunities and challenges for an increasing global business. Pharmaceutical Industry, being a highly research and knowledge driven global industry, is in the process of profiting from and adapting to these changes. This long lasting socio-medical-economic change will undoubtedly lead to a strong but different pharma industry in the future.

Generic APIs will …

M. Blocher (Dottikon): … have a considerable share of the pharma market as the population gets older, as healthcare cost pressure continues and as emerging economies progress.

Dr. A. Dietrich (Boehringer Ingelheim): … will benefit from the fact that the global pharmaceutical market is expected to continue growing overall and from the fact that over $100 billion in revenues in 2013 will be at stake due to patent expiry of blockbuster products. Here it is noteworthy, that the API world is divided into two types of producers. On the one side are the captive API producing pharma groups which exclusively manufacture APIs for their finished, branded products and on the other side are the so called third party manufacturers which serve the merchant market as supplier of APIs. The growth of the merchant API market for generic products has substantially outpaced the growth of the API for innovator products. As we know, many of these third-party manufacturing companies are located in Asia. China, in particular, is expected to increase its participation in this growth significantly. Even though the amount spent by emerging generic markets for medication is still small compared with those of Europe, North America and Japan, it nevertheless announces that generic drugs will most likely be responsible for the future growth of the pharmaceutical industry. China, India, South America and Russia consequently represent attractive growth opportunities for generic APIs.

H. Sieger (CU Chemie Uetikon): … be an important pillar of our future health care system and of Chemie Uetikon’s pharmaceutical custom manufacturing activities. It is likely, that branded Generics will be a success by reducing health care costs while providing high quality medication. This will hold true as long as manufacturing sites and processes do comply with highest, European standards and are not sacrificed for economical reasons by manufacturing in uncontrolled and unregulated markets.

The future of APIs is …

M. Blocher (Dottikon): … not overwhelming but sound. The pharmaceutical companies are concentrating on their core competencies of clinical research and development, patenting and distribution, and will increasingly seek out strategic cooperation with experienced, innovative and reliable partners in process development and manufacturing. Such chemical exclusive synthesis partners need to possess a versatile technology portfolio like a Swiss army knife and be as precise and reliable as a Swiss watch.

Dr. A. Dietrich (Boehringer Ingelheim): … is certainly driven by a number of exciting trends. We know that the global market for biopharmaceutical APIs is expected to grow continuously at approximately 4% per year. Average growth for large molecule-based APIs is outperforming the projected corresponding rate for chemically derived small molecule APIs. The majority of the worldwide market for biopharmaceutical APIs is located in Europe; North America and Japan show satisfactory growth rates. Only Asia promises an even better outlook for growth since the biosimilars market will grow more than the innovator’s biopharmaceutical APIs. When looking at the market for biosimilars, the potential is somewhat less defined when compared to chemically designed generic APIs, since it is still a more complex issue to establish a bioequivalence for a biopharmaceutical versus a chemically synthesized API. Consequently, this matter creates an uncertain regulatory framework for approving biosimilars in some parts of the world which needs to be addressed and solved. In addition, the costs of developing a biosimilar are more expensive due to the required time and resources needed for the protein analytics and clinical trials requirements. We believe that despite all these challenges there will be attractive market growth for these types of APIs down the road. Novel, chemically derived APIs will continue playing an important part in helping to bring new and innovative medicines to the market. Of course, managing cost early on will play an ever increasing role, independent of the life cycle stage the product is associated with. Lowering cost for already well established products has to be examined carefully and weighed against benefits. Reducing cost will more and more be designed early on into the discovery routes. In order to support such efforts, the various internal stakeholders from R&D, procurement up to operations have to work hand in hand to manage the total cost design of the final drug. There are many opportunities and challenges for novel and generic APIs in the future. Pharma companies have to be smart about the ways they can increase the economic value product by product.

H. Sieger (CU Chemie Uetikon): … most likely a future of more diversification. The age of block-busters is over. We will probably see an increasing number of highly specific drugs to treat rare diseases for rare or yet not treated diseases and for prevention rather than treatment. Preventative healthcare provides significant opportunities for Pharma industry and healthcare systems alike.

chemanager-online.com/en/tags/apis

General

Center Stage: Emerging Countries

All-round Pharma Service Providers See Potential in Asia, Elsewhere

Challenges – The challenges facing the pharma industry today – impending patent cliff, pressure coming from pharmerging markets, etc. – make the playing field rife with opportunities for pharma service providers.

Innovation in the pharmaceuticals ingredients industry is being driven by …

R. Hardy (Aesica): … the versatility of contract manufacturing organizations, which are now in a much stronger position because of their ability to offer a greater portfolio of services. The trend to outsource has been significantly shaped by the rising cost pressure on the pharmaceutical companies. Demand for pharmaceuticals has increased worldwide and this, coupled with improving standards of manufacturing facilities and rising cost pressure on companies, are the prominent factors contributing to the huge growth in the contract manufacturing sector. The pharmaceutical industry is facing several challenges, which lead to increased demand for contract manufacturing services. These include the rising cost of new product development, increasing competition in generic markets, declining R&D productivity, decrease in average patent life and government pressure to reduce drugs prices. In these circumstances contract manufacturing as a strategic option offers several advantages. Using an outsourced company provides flexibility, a quicker time to market and lower scale up costs. This means that emerging pharma and biotechnology companies can meet the growing demand for new drugs and focus on their core competencies. Furthermore, outsourcing enables companies to reduce excess capacity in their manufacturing networks and restructure supply chains.

Dr. R. Fink (BASF): … new APIs for the typical therapeutical areas. However, we think that lower solubility and bioavailability will become a significant challenge of our industry and requires intensified innovation efforts in the area of excipients. BASF is part of this innovation process by own R&D activities as well as together with its customers and partners.

B. Freiberg (Merck Millipore): … customer needs. In this industry, services and solutions are constantly evolving to improve customer productivity, minimize complexity and lower costs while reducing risk.

In 10 years, our industry will be …

R. Hardy (Aesica): … much stronger, competitive and diverse with the most significant contribution to the pharmaceutical market coming from emerging economies such as Brazil, Russia, China and India. In fact, the 2010 IMS Health forecast predicts that pharmaceutical markets in

Robert Hardy
CEO, Aesica

Dr. Ralf Fink
Vice President and Head of Pharma Ingredients at BASF

Burghard Freiberg
Senior Vice President Pharm Chemicals Solutions, Merck Millipore

emerging economies will grow at 14–17% year on year between now and 2014. These regions are expected to grow three times faster than mature markets due to a combination of evolving demographics including a rise in incomes, upgrading of health systems and an increased investment in the treatment of chronic diseases. Factors such as low-production cost and minimum taxes on production will ensure China is an attractive region for drug manufacturing and the export of pharmaceutical products from China has increased considerably during the last few years alone.

Dr. R. Fink (BASF): … different. Cost pressure, strong growth in emerging countries, ongoing market consolidation as well as the emergence of new regional or even global players and a significant higher demand for performance excipients are scenarios we want to be prepared for.

B. Freiberg (Merck Millipore): Redefined by forward thinking companies, like Merck Millipore, who are willing to push the envelope in the interest of innovating the pharmaceutical ingredients industry.

The most drastic change that has happened in the last 10 years is …

R. Hardy (Aesica): … the trend for large pharma companies to outsource various stages of the manufacturing process to minimize overheads and reduce capital investment. As they concentrate on R&D and focus on uncovering new compounds while investing in marketing and brand building, they are choosing to outsource all aspects of the manufacturing process to specialist providers. In particular, over course of the last five years there has been an increased demand for formulated products and packaging services. However, working with a partner that can provide a full service offering from formulation development through to commercial supply, packaging, as well as regulatory support is a unique proposition in the industry.

Dr. R. Fink (BASF): … the importance of the emerging economies and their increasing role along the whole value chain, including R&D.

B. Freiberg (Merck Millipore): … increased global regulation. Now more than ever, pharmaceutical companies are faced with regulatory pressures that need to be addressed. That is why partnering with an organization that deeply understands your challenges and can help assure the quality and safety of products you bring to market, is paramount.

For our business, Asia is …

R. Hardy (Aesica): … a critical market for Aesica and an area we're actively looking at expanding into. Aesica is already a global business with six manufacturing facilities in our growing portfolio. However, further expansion is planned and we are looking at opportunities for strategic acquisitions and the potential of forming long-term partnerships in the U.S. and Asia, especially India, as we look to grow the business further globally.

Dr. R. Fink (BASF): … very important, fascinating and challenging. We are keen to play an even more active role in that part of our world.

B. Freiberg (Merck Millipore): Essential. We are striving and continuing to build relationships in Asia that will allow us to expand our reach and provide customers – in this rapidly developing market – with innovative products and solutions to meet their goals. We are deeply committed and invested (more than 30 years) to increasing innovation and the quality of the drugs that are made in the region.

Governmental healthcare reforms and cost-reduction plans will …

Dr. R. Fink (BASF): … continue.

B. Freiberg (Merck Millipore): Drive innovation in the market and ensure that manufacturers will continue to streamline processes (while advancing technology) to deliver the best possible product to the market.

chemanager-online.com/en/tags/pharma

EVENTS

The ChemShow, Nov. 1–3, New York City Showcasing the latest process equipment, products and technology, the Chem Show brings together manufacturers and innovative new suppliers with executives, process engineers, production teams and plant personnel.

▶ www.chemshow.com

Expoquimia 2011, Nov. 14–18, Barcelona This year's show will be putting an emphasis on the scientific side of chemicals, with a program of conferences, seminars and other activities. Expoquimia aims to provide solutions for emerging markets, such as alternative energies, biotechnology, industrial pharmaceuticals, fine chemicals and food-related sectors.

▶ www.firabcn.es

10th Annual World Drug Manufacturing Summit, Nov. 29–Dec. 1, Berlin Now in its 10th year, World Drug Manufacturing is firmly established as the must attend event for small molecule and biologic manufacturers. Over the course of the three days, the industry will gather to discuss many hot topics. The 2011 WDM program will address the major issues affecting the pharmaceutical and biotech industries at the current time, such as change management; cost reduction; changing product portfolios; and much more.

▶ www.wdmsummit.com

Industrial Green Chemistry World- Symposium & Expo (IGCW 2011), Dec. 4–6, Mumbai Industrial Green Chemistry World is India's first flagship platform that brings together mainstream issues concerning Green Chemistry and Green Engineering (GC&E) to all Chemical Industry stakeholders. At the IGCW 2011, you can be assured of in-depth exposure to diverse and successful endeavors in the industry and bring on par your technological and business practices with world leading practices and global trends in GC&E.

▶ www.industrialgreenchem.com

European Chemical Region Network 2011 Congress in Germany

The chemical industry has played a vital role in the industrial sector in Saxony-Anhalt, Germany, for many years now. Generating 14% of overall turnover and employing 9% of the total workforce, it has a leading position among the various industries in the federal state of central Germany. In terms of exports, it is top of the pile. The chemical industry makes up one fifth of all industry export turnover in Saxony-Anhalt.

So, it's all the more pleasing that the local chemical industry has had such a strong start to 2011. At the home of the central German chemical industry, turnover from January to March rose to €1.9 billion. Seasonally adjusted in comparison with the previous quarter, turnover has risen by more than 21%. Compared to the same quarter the previous year, business volume has risen by a third. The main impetus behind this rapid development has been the classic chemical industry. The pharmaceutical industry has contributed nearly €300 million to this sector's turnover in the federal state.

"Investing in innovations is an absolute necessity if we want to continue to drive growth forward and ensure competitiveness, because knowledge is increasingly becoming a decisive production factor," said Prof. Dr. Birgitta Wolff, Minister for Science and Economy in Saxony-Anhalt and president of the European Chemical Regions Network (ECRN).

ECRN currently brings together 21 chemical regions from across Europe. This year's 9th Congress of the European Chemical Regions Network, will be held at Oct. 27 in Halle/Saale Germany. This year the congress host is the federal state of Saxony-Anhalt in central Germany and the organizers expect a range of high-ranking representatives from politics, business, academia and public authorities to put a spot on the European regional policy.

Particularly the potential and challenges of sustainable use of structural funds in the European chemical regions in terms of the Europe 2020 Strategy will be one of the main topics.

The congress aims to support the exchange of views and experiences from different stakeholders in the chemical sector at a European level and fruitful discussions with representatives from the European Commission, the European chemical industry associations, unions and the member regions.

Additionally visitors are free to attend the workshops "Demographic Change", "New ways in the politics of innovation" and "The contribution of chemical logistics to the maintenance of the competitiveness of the chemical industry in Europe." The report of Prof. Dr. Birgitta Wolff on the active role of the German federal government in developing European transport corridors to create the base for chemical logistics completes the congress program.

▶ www.ecrn.net
www.investieren-in-sachsen-anhalt.de

PEOPLE

Thomas Büttner

Büttner New AllessaChemie President and CEO Dr. Thomas Büttner became AllessaChemie's president and CEO on Oct. 1. Büttner, who has been directing the company's group functions since May 1, takes over from Almuth Poetz. He began his career in chemicals in 1984 with Rütgerswerken in Frankfurt, where he worked in various subsidiaries in several different positions until 2003. Before joining AllessaChemie in May, he was managing director at WeylChem and Sensient.

Michael Träger

Träger Reelected as Euro Chlor Chair Michael Träger, managing director and COO of Vestolit, has been reelected as chairman of Euro Chlor for another one-year term. This re-election is the logical consequence of a change in the Euro Chlor statutes to extend the term of the management committee chairman to two years. Träger has been involved with Euro Chlor activities for over 11 years. During his chairmanship, he said intends to help further develop the new and improved sustainability program for the coming decade in order to foster and strengthen the achievements of the chlor-alkali industry's reputation and its sustainable contribution to a safe and healthy community.

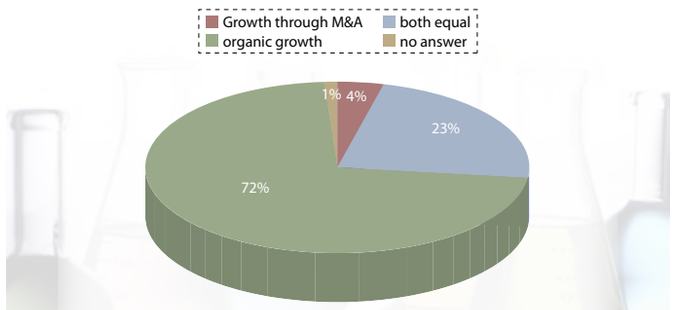
Kenneth Frazier

Merck & Co. Announces New Chairman Merck & Co. announced the retirement of its chairman Richard Clark, effective Dec. 1. Kenneth Frazier, president of chief executive officer will succeed as chairman. Clark has been with the company since 1972 and served as chairman since 2007. He was president and chief executive officer from 2005 through 2010. From the role of quality control inspector, he progressed through increasingly responsible roles. He left the company to join Merck-Medco Managed Care subsidiary as executive vice president and chief operating officer. He later became the chairman, president and chief executive officer of Medco Health Solutions. In 2003 Clark rejoined Merck as president of manufacturing division.

CHEMonitor: Focus on Sustainability

Growth Strategies Graphic 1

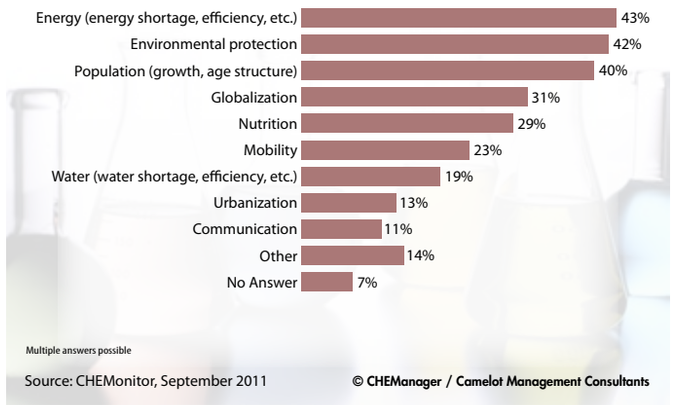
Which growth strategies will your company be following over the next 12 months?



Source: CHEMonitor, September 2011 © CHEManager / Camelot Management Consultants

Megatrends and Corporate Strategy Graphic 2

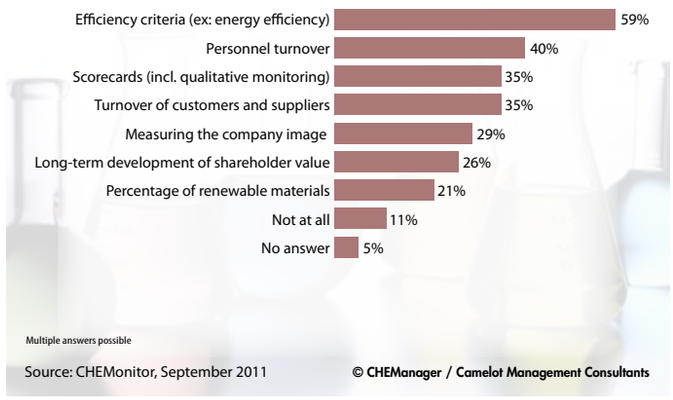
Which megatrends does your corporate strategy follow?



Source: CHEMonitor, September 2011 © CHEManager / Camelot Management Consultants

Corporate Sustainability Graphic 3

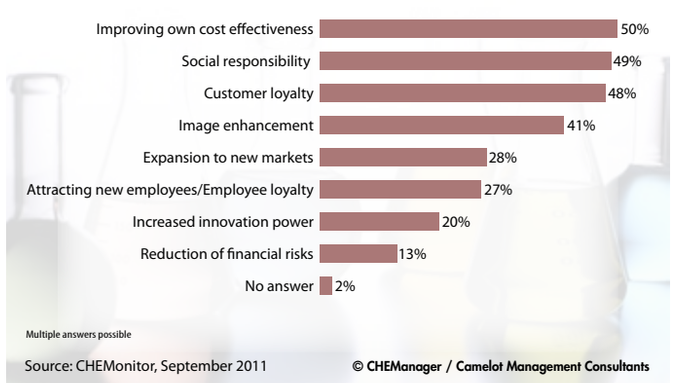
How do you measure your company's sustainability?



Source: CHEMonitor, September 2011 © CHEManager / Camelot Management Consultants

Sustainable Corporate Strategy Graphic 4

Where do you see the biggest advantages of a sustainable corporate strategy for chemical companies? Name three important topics.



Source: CHEMonitor, September 2011 © CHEManager / Camelot Management Consultants

Three times a year, CHEMonitor – a cooperation between CHEManager and Camelot Management Consultants – examines the current trends and developments in the chemical industry. This time, managers, board members and decision makers in the chemical industry were asked about sustainability.

When asked about their company's growth strategy, 72 % of those asked said they are relying on organic growth; this is up from 11 % in January (graphic 1). Only 4 % of those asked said that they plan on achieving growth through M&A activities. In order to achieve sustainable management and growth, more and more chemical companies are tailoring their strategies to meet the current mega trends. These trends have a half life of at least 50 years, are widely immune to set backs and usually affect many parts of daily human life in different cultures. They change forms of civilization, technology, economies and value systems. According to the most recent CHEMonitor, the mega trends energy (43 %), environmental protection (42 %) and population (40 %) are very close together (graphic 2). However, all three trends were able to gain importance in terms of chemical industry strategy when compared with CHEMonitor results from May 2007 and August 2009. Futhermore, the mega trends mobility (+ 15 % over 2009) and water (+ 7 % over 2009) were able to win significance over the last two years.

One example of an innovative product that caters to several mega trends is the superabsorber Stockosorb from Evonik. The polymer can absorb many times its weight in water, which it can then release to plants as necessary. It can be used to increase the survival for young argan trees in Morocco. These trees provide the population with wood, animal feed and oil; their population has been in rapid decline over the last several years. The company recently won the Cefic Responsible Care Award for the development.

Almost 60 % of those asked said that efficiency criteria, particularly energy, were the most important indicator when it comes to measuring the sustainability of a chemical company (graphic 3). Close behind was personnel turnover, which 40 % of the chemical company managers named as a parameter. Such fluctuation was particularly seen by smaller companies (< 50 employees) as the top indicator for sustainability (48 %)

When asked about the advantages of a sustainable corporate strategy, almost half of all the chemical company managers listed improving own cost effectiveness; taking social responsibility; and customer loyalty (graphic 4). A much smaller percentage – 20 % – drew a correlation to an increase in innovation power. Camelot chemicals expert Dr. Sven Mandewirth said: "The advantages of a sustainable innovation strategy is often underestimated. Sustainable growth requires innovative ideas all along the value chain – from changing the raw material base all the way to returning the end product for reuse."

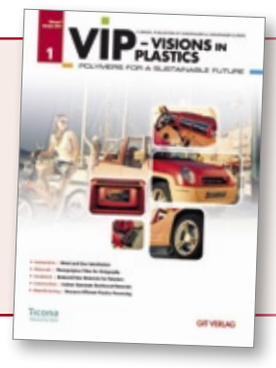
Source: CHEMonitor, CHEManager 19/2011

World's Largest POM Manufacturing Plant After three years of construction, Celanese recently opened its state-of-the art polyoxymethylene (POM) production facility in Frankfurt Hoechst Industrial Park, Germany. The company said it is the world's largest acetal copolymer production plant, with a nameplate capacity of 140,000 tons per year. The company said the new plant will strengthen Ticona's engineering polymers business. Ticona is Celanese's engineering polymers business. The new manufacturing facility is expected to meet the increased global demand for innovative specialty solutions in polymer-based products.

This issue of CHEManager Europe contains the special supplement

ViP – VISIONS IN PLASTICS

A SPECIAL PUBLICATION OF CHEMANAGER & CHEMANAGER EUROPE



Coming up in our November issue

- **Dr. Christian Jochem of the European Process Safety Centre examines climate change and plant security**
- **Bayer's Christian Drumm looks at energy efficiency management and benchmarking**
- **Ruben Gill of AspenTech explains how software solutions can achieve success for speciality chemicals manufacturers**
- **Irina Steer of Süd Chemie writes about how second generation biorefineries can contribute to a bio-based economy In Europe**
- **And much more!**

The November issue of CHEManager Europe will be published on Nov. 10.

Index

Imprint

Publisher:
GIT VERLAG
Wiley-VCH Verlag
GmbH & Co. KGaA
A Company of
John Wiley & Sons, Inc.

Geschäftsführer
Christopher J. Dicks,
Bijan Ghawami

Director
Roy Opie

Product Management
Dr. Michael Reubold
Tel.: +49 6201 606 745
michael.reubold@wiley.com

Editor-in-Chief
Brandi Schuster
Tel.: +49 6201 606 755
brandi.schuster@wiley.com

Editorial
Dr. Roy Fox
Tel.: +49 6201 606 714
roy.fox@wiley.com

Wolfgang Siess
Tel.: +49 6201 606 768
wolfgang.siess@wiley.com

Dr. Birgit Megges
birgit.megges@wiley.com

Media Consultants
Corinna Matz-Grund
Tel.: +49 6201 606 735
corinna.matz-grund@wiley.com

Thorsten Kritzer
Tel.: +49 6201 606 730
thorsten.kritzer@wiley.com

Ronny Schumann
Tel.: +49 6201 606 754
ronny.schumann@wiley.com

Roland Thomé
Tel.: +49 6201 606 757
roland.thome@wiley.com

Team Assistants
Lisa Rausch
Tel.: +49 6201 606 742
lisa.rausch@wiley.com

Beate Zimmermann
Tel.: +49 6201 606 764
beate.zimmermann@wiley.com

Freelancers
Dr. Sonja Andres

Production Managers
Christiane Potthast
Claudia Vogel (Advertising)
Oliver Haja (Layout)
Ramona Rehbein, Elke Palzer (Litho)

Reprints
Dr. Katja Habermüller
Tel.: +49 6201 606 719
katja-carola.habermueller@wiley.com

Subscription/Reader Service:
Silvia Amend
Fax: +49 6201 606 700
silvia.amend@wiley.com

Bank Account
Commerzbank AG Darmstadt, Germany
Account No. 01715501/00,
Routing No. 50880050
The current price list is valid from 1st October 2011

CHEManager Europe appears 10 times in 2011.

Print run: 20,000
(IVW Report
Q2 2011: 19466 tvA)
Seventh year 2011
Subscriptions
10 issues €84
incl. postage
single copy €13.50
plus postage

Students receive a discount of 50 % upon presentation of a valid certificate. Subscription orders can be canceled within 1 week in writing. Dispatch complaints are possible only within 4 weeks after publishing date. Subscription cancellations are accepted 6 weeks before end of year.

Orginal Articles
Specially identified contributions are the responsibility of the author. Manuscripts should be addressed to the editorial office. Instructions for authors may be requested from the publishing company. We assume no liability for unsolicited, submitted manuscripts. Reproduction, including excerpts, is permitted only with the permission of the editorial office and with citation of the source.The publishing company is granted the exclusive, space and content restricted right to arbitrarily use the unmodified work/editorial contribution for all purposes for itself and for businesses that have an interest in the publishing company as defined by company law as well as to transfer the right of use to third parties. This right of use applies to both print and electronic media including the internet and data banks/data media of all types.
All names, designation, or signs in this issue, whether referred to and/or shown, could be trade names of the respective owner.

Printed by
Druckzentrum Rhein-Main
GmbH & Co. KG
Alexander-Fleming-Ring 2
65248 Rüsselsheim

The Deutsche Presse Agentur (dpa) retains all copyright and other intellectual property rights in the dpa material. The dpa material is for the purpose of private information only. It is not permitted to distribute, sell, forward and pass on any of the dpa material to any other person or entity, and nor is it allowed to archive and store any of the dpa material, unless agreed otherwise in a separate agreement with dpa. All rights reserved.

GIT VERLAG

Printed in Germany
ISSN 1861-0404